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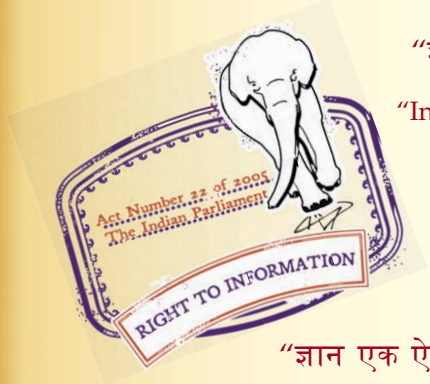
IS 12430 (1987): Safety code for installation, maintenance and servicing of sterlizers [MHD 14: Hospital Planning]



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"Knowledge is such a treasure which cannot be stolen"

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IS : 12430 - 1887
(Reaffirmed 1997)

Indian Standard

SAFETYCODEFOR INSTALLATION, MAINTENANCEAND SERVICING OF STERILIZERS

UDC 615·478·73·004·5 : 614.8

BUREAU OF 'INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Gr 15

July 1989

CONTENTS

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Indian Standard

SAFETY CODE FOR INSTALLATION, MAINTENANCE AND SERVICING OF STERILIZERS

0. FOREWORD

0.1 This Indian Standard was adopted by the Bureau of Indian Standards on 14 July 1987, after the draft finalized by the Hospital Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This safety code is intended as a guide for medical personnel and engineers, both specialists in sterilizers and sterilizing procedures, and those responsible for their maintenance. It is also intended for pharmacists and sterile supply administrators. It is anticipated that the code will prove useful to supplies officers, architects, service engineers and to others not directly involved in sterilizers but who may have an interest.

0.3 The best working of the sterilizers could be ensured by:

a) optimum decontamination by suitable cleaning equipment and process, as meticulously as possible, with bacteriological monitoring;

b) use of suitable packing materials and size of packs;

c) sterilizing, preferably, similar materials in a process;

d) using, preferably, different sterilizers appropriate for their use;

e) appropriate loading of sterilizers; and

f) suitable handling/transportation/use of sterilized packs.

0.4 In the preparation of this code, assistance has been derived from 'Health Technical Memorandum: Part 10 Sterilizers', issued by the Department of Health and Social Security, U.K.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS :2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Rules for rounding off numerical values (*revised*).

1. SCOPE

1.1 This safety code gives guidance to hospitals and other users of sterilizers regarding the choice, purchase, installation, testing and commissioning, use, maintenance and servicing of steam sterilizers used for porous loads, fluids in sealed containers and unwrapped instruments and utensils. It gives similar guidance on electrically heated sterilizing ovens (hot air sterilizers).

1.2 Guidelines on sterilizers working on low temperature ethylene oxide, formaldehyde, and radiation shall be considered separately.

1.3 The sterilizers described in this code may not be suitable (without modification) for safely processing of articles infected with Category A pathogens*.

*Organisms so **dangerous as to present great risks to the health either of laboratory workers or of the human or animal communities,**

2. GENERAL INFORMATION

2.1 Close limits have to be placed upon the quality of steam supplied for most sterilizing purposes. The problems are considered in depth in Appendix A. Steam for sterilizers, other than those for bench top use, is normally obtained from the hospitals mains. The disadvantage of other methods of steam raising are also discussed in Appendix A. Independent steam generators should be used only where there is no practical alternative.

2.2 It is usually counter-productive to conserve energy by shutting off the steam supply to jacketed sterilizers during any part of the day or night during the normal week, and it is also preferable to keep the steam on the jackets during the weekends.

2.3 The correct functioning of a sterilizer can best be monitored by fitting and intelligent use of reliable instruments on the machine and by use of other high quality instruments for commissioning and periodic checking of sterilizer and the

instruments fitted to it. Appendix B which deals fully with all aspects of the subject, has been closely studied in conjunction with sterilizer and industrial instrument industries.

2.4 It is essential that proper provision be made for entry of thermocouples into the sterilizer chamber.

2.5 Appendix C indicates the space required around sterilizers for maintenance purposes and service requirements for them.

2.6 Many technical advances have taken place in recent years in the design of sterilizers and their associated cycles. These advances shall continue for many years to come. It is essential, therefore, that sterilizers for a particular scheme are not ordered and stored on site for long periods but are deliv ered, installed, commissioned and put into service with the minimum of delay. Failure to observe this procedure will often result in installation of a technically obsolete sterilizer.

2.7 Continuous control of sterilizing cycle can be based upon the intelligent use of instruments, careful commissioning, adoption of a properly designed planned preventive maintenance (PPM) programme and the regular comparison of temperature records of production cycles with corresponding records obtained during commissioning. This requires close and continuous collaboration between engineers and operators, the details of which are given in Appendix D.

2.8 The commissioning of sterilizers is covered in 7.11. Appendix E is a check-list of pre-commissioning procedures and commissioning tests; all other tests are covered in Appendices G to N.

2.9 Appendix D deals with operation and maintenance in considerable details.

2.10 Appendix F summarizes all tests required on sterilizers. Appendices G to N describe in detail the various tests required for porous loads, fluids, unwrapped instruments and utensils and hot air sterilizers.

3. DEFINITIONS, POLICY AND IMPLEMENTATION

3.1 Terms and abbreviations used in this code have the following definitions.

3.1.1 *Engineer/Sterilizer Engineer* — This person should have a specialist knowledge of sterilizers and sterilizing procedures, He wilt be required to liaise closely with professionals at various levels, and it is preferable that he should be a qualified engineer and should be conversant with sterilizers and have received specific training on sterilizers and their maintenance.

3.1.2 *Operator* — Any person who operates a steriiizer under the guidance of an engineer.

3.1.3 *Batch* — The contents of one load of a sterilizer ('batch' and 'load' are synonymous in this standard).

3.1.4 *PPM* — Planned preventive maintenance.

3.1.5 *TRC* — Temperature recorder chart; a complete chart recording from a temperature recorder fitted permanently to the machine.

3.1.6 *MTR* — Master temperature record; MTR is required for each type of batch of medicinal products processed by a fluids sterilizer and each type of load processed by hot air sterilizer as agreed by the user. MTR is not normally required for a porous load sterilizer nor for a sterilizer for unwrapped instruments and utensils except for reference by engineers. It is a transparent 1 : 1 undistorted copy of an acceptable temperature record chart obtained by the engineer after satisfactory commissioning by the contractor, or subsequently. The original is retained with the commissioning documents by the sterilizer engineer. A new MTR is also required after any sterilizer used for processing medicinal products and any hot air sterilizer is re-commissioned.

A typical example is given in Appendix P.

3.1.7 *Saline* — Solutions of chloride salts such as are processed in sterilizers described in this code.

3.2 Abbreviations for departments with centralized sterilizing functions are as given below:

a) TSSU — Theatre sterile supply unit,

b) CSSD — Central sterile supply department, and

c) HSSU — Hospital sterile supply unit.

3.3 Policy and Implementation

3.3.1 There are five principal classes of load to be sterilized:

a) Porous loads,

b) Fluids in sealed containers,

c) Unwrapped utensils and instruments,

d) Equipment and materials for asceptic manufacture of medicines, and

e) Materials associated with specific pathogen free (SPF) procedures.

3.3.2 The use of sterilizers with a door at each end assists in segregation of processed from the unprocessed.

3.3.3 Sterilizers of the same class in a particular installation should generally be of the same size and made by the same manufacturer.

3.3.4 It is a normal practice for the manufacturer of the sterilizer to be either the contractor for the supply only or for the supply, installation

and commissioning of the machine. Where the term 'manufacturer' is used in this standard, it is to be construed as if it includes the obligations of the contractor.

3.3.5 The importance of close and continuing collaboration between engineers and those responsible for the production of sterile supplies, including sterile medicinal products, cannot be too highly stressed.

3.3.6 Reserve sterilizing capacity should always be available so that it is possible to withdraw a sterilizer for planned maintenance purposes and periodic testing in normal working hours without jeopardizing production; production schedules should be arranged accordingly.

3.3.7 Consideration must be given to the use of a CSSD or other similar centralized service before replacing any sterilizer which is not in a centralized department, and before purchasing any new sterilizer for use anywhere else in a hospital.

3.3.8 Intending purchasers of sterilizers are recommended to study the current editions of the relevant Indian Standards in conjunction with this code.

4. TYPES AND OTHER REQUIREMENTS OF STERILIZERS

4.1 Types of Sterilizers

4.1.1 ***Sterilizers for Porous Loads and Instruments*** — These sterilizers are intended to deal with dressings, textiles and equipment made of rubber, such as gloves, wrapped instruments and wrapped utensils. Sterilizers in this category must have means to remove air from the chamber and load prior to the admission of steam for sterilization, and to dry the load under vacuum after sterilization.

4.1.2 ***Sterilizers for Fluids in Sealed Containers***

4.1.2.1 The sterilizers should have the following optional extras:

a) Means to accelerate cooling by use of cooling water sprayed over the fluid containers, and

b) Means for sterilization of fiuids in plastic bags by maintaining equilibrium pressure conditions between the inside and the outside of the bags (air ballasting).

4.1.2.2 When accelerated cooling, or air ballasting systems, or both are used, it is essential to establish that the containers shall remain sealed throughout the process.

4.1.2.3 It should not be possible to open the door of a sterilizer until the temperature of the contents of the containers has **falled** below 70°C.

CAUTION- Failure to observe this requirement may lead to serious accidents resulting from the explosion of containers.

4.1.2.4 Fluids in some non-rigid containers do not present the same hazard, and it may be necessary to remove them from the sterilizer at a temperature in excess of 70°C for operational reasons.

4.1.3 ***Sterilizers for Unwrapped Instruments and Unwrapped Utensils*** — Instrument and utensils sterilizers are intended to deal with unwrapped instruments and unwrapped utensils within a complete cycle time of approximately 10 minutes.

4.1.4 ***Small Electrically Heated Steam Sterilizers for Unwrapped Instruments and Utensils*** — These are normally used for similar duties to those in 4.1.3 above, but have internal steam raising equipment and the cycle time may be longer, for example, a cycle may take 20 minutes from cold. The sterilizers are free-standing and do not require any piped services. Demineralized or distilled water, for example, purified water, must be used in them and they must not be allowed to boil dry.

4.1.5 ***Hot Air Sterilizers*** — Hot 'air sterilizers are dry air ovens, operating at ambient pressure and should comply with IS : 3119-1978* except as indicated in 11; in particular, it is recommended that they can be automatically controlled and be fitted with door locks.

4.2 Sizes of Sterilizers and the Number Required

4.2.1 ***Sterilizers for Porous Loads*** — It is difficult to give precise information on types and sizes of sterilizers required for particular hospitals because in practice, there are substantial variations in patterns of use. It is recommended that when assessing the number and size required, the bulk volume of the work load to be handled should, if possible, be measured, such as by reference to the present source of supply for sterilizing. The size and number of sterilizers necessary can then be calculated having regard to the work load, bulk volume and the number of productive cycles which are practicable within the intended working hours. A porous load sterilizer is required to complete its cycle of operations in not more than 30 minutes. The drying stage time is, however, sometimes extended when the sterilizer is used for processing trays of instruments and other difficult loads. If the total cycle time is to be extended, this must be allowed for when calculating the number of sterilizers required. The preferred chamber size for porous load sterilizers is 600 × 900 × 1 200 mm and above.

*'Specification for hot air sterilizers (*first revision*).

4.2.2 ***Sterilizers for Fluids in Sealed Containers*** — *It* is generally accepted that the best method of providing sterile fluids is by the use of individual container, for example, 1 litre and 500 ml bottles. The size of sterilizer required shall be determined by the number of containers to be sterilized in a given time. The daily load may be dealt with in one cycle of several hours' duration or by several shorter cycles, using a rapid cooling device. If a rapid cooling device and/or air ballasting is required, this must be specified by the purchaser.

4.2.3 ***Sterilizers for Unwrapped Instruments and Unwrapped Utensils*** — Where in existing hospitals, separate rapid cycle sterilizers are required for individual theatres, one sterilizer 400 mm in diameter and 600 mm long is generally sufficient to meet the needs of a single operating theatre.

4.2.4 ***Small Electrically Heated Steam Sterilizers for Unwrapped Instruments and Utensils*** — These usually have cylindrical chambers and the most commonly used machine has a chamber 200 mm in diameter and 300 mm long. They are generally fitted with up to four removable trays about 150 × 300 mm. These sterilizers may be used in theatre suites (1 per pair of theatre) where there is no TSSU, and in certain other clinics.

4.2.5 Hot ***Air Sterilizers*** — The chamber size of the oven most suitable for use is 450 × 450 × 400 mm. In any specialist unit where there is a high usage of this type of equipment (for example, ophthalmology), the demand would be met by a number of units of this size.

5. NOISE AND VIBRATION LEVELS

5.1 General

5.1.1 The overall noise level anywhere in a room containing the sterilizer(s) should not exceed the following levels for more than 10 minutes at one stretch in an interval of one hour:

a) CSSD: 70 dB,

b) Operating theatre suites, pharmacies and treatment rooms: 55 dB, and

c) Other noise sensitive areas: **60** dB.

5.1.2 In nonsensitive areas, the maximum poise level anywhere in the room should not exceed 85 dB. The above levels are for an area or space when the sterilizer is operating under normal working conditions. The Jevels include noise from all sources including the sterilizer.

5.2 Mean Near-Field Sound Pressure Level

5.2.1 The mean near-field sound pressure level of each sterilizer should be determined in accordance with IS : 4758-1968*.

*Methods of measurement of noise emitted by machines.

5.2.2 The mean near-field sound pressure level should be found for the noisiest part of the sterilizer cycle from at least five readings on a reference radius of 0·3, 1·0, 3·0 or 10·0 m centred on the geometric centre of the equipment. The reference radius should be less than twice the leading dimension of the equipment or that part of the equipment being tested. In the case of built-in sterilizers, the geometric centre should be that of the projection into the user space, and the leading dimensions shall be the projection from the fascia.

NOTE — Transient noise of less than 5 seconds duration., that is, between different parts of the cycle, may be Ignored.

5.2.3 The measured mean near-field noise level of the sterilizer should be less than the general levels given in 5.1.1 above when reduced as appropriate as follows:

a) Generally, if there is only one or two pieces of major noise producing equipment, not necessarily all sterilizers, operating at the same time in the room under consideration, the reduction should be 50dB for each sterilizer;

b) If there are three noisy items, the reduction should be 7 dB;

c) For four and five items, 8 dB;

d) For six items, 9 dB; and

e) For seven or more items, 10 dB.

5.3 Installation Considerations

5.3.1 The room in which the sterilizer is to be installed should be planned and designed so that the noise transmitted from the room does not give rise to excessive noise levels in adjoining areas.

5.3.2 Open louvers in walls and internal doors should be avoided if the sterilizer room is in or adjacent to a main building or a noise sensitive area. In such situations, the doors should be self-closing and a good fit in their frames, preferably with compressed rubber seals. This may prevent natural ventilation and mechanical ventilation may, therefore, be required as detailed elsewhere.

The need for such a solution can usually be avoided in the planning stage. The fascia panel cannot always be relied upon for sound attenuation, for example, when it incorporates louvers or sliding doors.

5.3.3 The total vibration transmitted through the supporting feet and service connections to the

building structure should not exceed the amplitud es given below at any part of the cycle or under any load condition:

Octave *Band Mid-Frequency*	*Maximum Acceptable Vibration Amplitude*
HZ	mm
2	0·04
4	0.025
8	0.014
16	0·007
32	0·003
63	0·001

NOTE — Transient vibrations of greater amplitude than those above may be tolerable, if of short duration.

5.3.4 If vibration is likely to be a problem in a particular situation, it is recommended that:

a) The whole sterilizer assembly be secured on properly designed anti-vibration mounts,

b) Vibration transmission through service connections should be avoided by use of suitable flexible connections, and

c) Pumps and motors associated with sterilizers should be resiliently mounted whether or not they are integral with the main unit.

6. SPECIFICATIONS TO BE INCLUDED IN HOSPITAL TENDER DOCUMENTS

6.1 General Specifications

6.1.1 The specification should state that the sterilizer must comply with the apropriate Indian Standards and with any additional requirements as indicated in this code.

6.1.2 Hot air sterilizers should meet the specification of IS :3119-1978* except that the maximum error of the thermometer should be in accordance with B-2.4. These sterilizers should also be fitted with high temperature limit switches and the doors should be able to be locked.

6.1.3 All invitations to tender for sterilizers should request full information from the manufacturers (see Note below) on all services and connections to be provided by the hospital for operating the sterilizers. Manufacturers should also be required to state the maximum flow rates, the minimum and maximum acceptable pressure and the maximum consumption of each service for one cycle of the largest load.

NOTE — It is normal for the manufacturer of the sterilizer to be the contractor for its supply and/or installation. The term 'manufacturer' in this code relates to the manufacturer as such or in his capacity as contractor. In this code, the term contractor is used when it specifically refers to the manufacturer in his capacity as a contractor, in particular as an installation contractor (or sub-contractor).

***Specification for hot air sterilizers (*first revision*).**

6.1.3.1 The services required may include the following:

a) Steam supply (*see* Appendix A);

b) Electricity — the specification should state the type of supply available, that is, voltage, frequency and number of phases (local or integral steam generators usually result in high electrical loading);

c) Water supply for condensers, water sealed pumps and occasionally for rapid cooling devices on sterilizers for sealed fluid containers (the fitting of temperature limiting valves and other devices to reduce water consumption should be encouraged (see also 7.6.1);

d) Condensate return from the jacket, steam separator and traps;

e) Open gravity drain, except for effluent containing harmful gases or pathogenic material, in which case special closed and protected drainage systems may be necessary;

f) Waste cooling water outlets from condensers; and

g) Compressed air (air ballasting on some bottled fluids sterilizers and for air operated valves or other mechanisms on some sterilizers).

6.1.4 The manufacturer should state the heat energy released under continuous full load operating conditions when the ambient temperature in the adjoining rooms is 27°C in a period of one hour in:

a) the operating area, and

b) the maintenance area.

6.1.5 The controls and instruments must function correctly under the worst summer conditions, that is, at 48°C in the plant room.

6.1.6 The manufacturer should be given sufficient information to enable him to confirm that the noise and vibration level after installation shall not exceed that specified for the location, as in 5.

6.1.7 Clear and simple instructions for operating the sterilizer should be prominently displayed in indestructible form and preferably on or near the operating panel. These instructions should be suitable for the guidance of staff unfamiliar with the machine.

6.1.8 The type and standard of packing for delivery of the sterilizer should be specified unless the manufacturer is to be responsible for the installation of the machine.

6.1.9 Consideration must be given to the probable conditions of installation (for example, whether the machine will be installed and used at once or will be positioned adjacent to building operations in dusty conditions, or will stand on the site unconnected for a long period). It may be necessary in some cases to specify dustproof packing and a substantial transit case to prevent damage on site.

6.1.10 The manufacturer should be required to supply two complete sets of technical literature on operation, maintenance and overhauling of all major functional items of equipment incorporated in the sterilizer, as well as two copies of record drawings showing the pipework and electrical circuits on the machine itself. This should indicate all parts which should be held in stock and may require replacement during the normal working life of the sterilizer. The literature must include a complete PPM programme.

Thus it must show the tasks to be performed weekly, three-weekly, six-weekly, quarterly, half-yearly, yearly and multi-yearly.

6.1.11 The manufacturer should also be required to provide, at the time of tendering, details of routine tests suitable for determining sensitivity of the air detectors fitted to porous load machines made 'by him and details of any extra devices and thermocouples required to be supplied or fitted by the user for the purpose of conducting the test.

6.1.12 Adequate arrangements will be required for regular servicing of sterilizers and early consideration should be given to the nature of the arrangements. If contract servicing is necessary, enquiries on terms and conditions of a suitable contract should be made at the time when the tenders are issued.

6.1.13 The manufacturer should be required to tender for quarterly maintenance inspections during the first year and to submit written reports promptly on the result of each inspection unless this is automatically provided under the guarantee. The contract will not normally cover daily, weekly, three-weekly or six-weekly maintenance which must start at hand-over.

6.1.14 The manufacturer should be required to undertake to replace, free of cost to the purchaser, any part of the sterilizer found, within 12 months of the handing-over date, to be defective due to faulty materials or workmanship or poor design.

6.2 Particular **Specification**

6.2.1 The specification should be based on Indian Standard specification amended as necessary to conform with the requirements of this code.

6.2.2 Adequate details of design of proposed location of the sterilizer and the appropriate noise level should be stated clearly in the specification.

6.2.3 Side, back and top panels of free-standing sterilizers should be easily removable and replaceable for maintenance purposes.

6.2.4 Power-operated doors are desirable on porous load and fluids sterilizers of 300 litres capacity and above. Designs available at present are :

a) Sliding doors (vertical or horizontal), and

b) Side-hinged doors.

6.2.5 In 6.2.4 (a), the possibility of operator touching the hot inside face of the door is reduced. Other considerations may influence the choice of door operating system in any particular installation, for example, work load, space restrictions, price and ease of maintenance. Vertical chamber sterilizers require special guards to ensure the safety of the operator when the chamber is being lowered.

6.2.6 If the capacity of the sterilizer chamber exceeds 600 litres, a device shall preferably be fitted so that the door can be secured open by a lock, the key of which can be removed and kept by a person entering the chamber.

6.2.7 The door control mechanism should perferably incorporate a safety device which will prevent the entry of steam until the door is fully closed and secured. This feature should remain operative at all times, including during a manual operation of the machine and/or failure of any service to the machine. The requirement does not apply to sterilizers in which steam is generated within the chamber itself.

6.2.8 The specification for any sterilizer required to have a door at each end should ensure that it meets the following additional requirements during normal operation:

a) It should not be possible to have both doors open at the same time;

b) The automatic process control, when provided, should be operated from the unsterile side only;

c) A device should be provided at each end of the sterilizer indicating 'DOORS LOCKED' when both doors are closed and secured; and

d) The chamber pressure gauge should be provided at the unloading end in addition to any process indication fitted at the loading end of the sterilizer.

NOTE - The machines shall be installed for unidirectional flow.

6.2.9 If hinged doors are required, the specification should state whether these are to be hinged on the left-hand or right-hand side of the opening when facing the machine, or whether either is acceptable.

6.2.10 The door should be readily accessible for cleaning, adjustment and replacement.

6.2.11 Sterilizers designed to be built into a pre-formed recess are not necessarily made so that there are no gaps between the front and the rear of the unit. Exceptionally, where it is necessary that the area in which the sterilizer is operated must be completely sealed from the machine maintenance areas to prevent the transfer of micro-organisms (for example, animal research laboratories), the requirement must be clearly stated in the specification.

6.2.12 In the event of a sterilizing stage failure on an automatically controlled machine a 'NON-STERILE' sign should automatically be illuminated and an audible alarm should sound. A switch may be provided to mute the alarm but it should NOT extinguish the illumination of the sign until the door is released. The door must be so interlocked that on a sterilizing failure, it will not be released until some special manual action has been taken. This usually involves the use of a key.

6.2.13 Any control which is variable but preset, should be accessible only to authorized persons.

6.2.14 Means must be incorporated to enable the engineer or other authorized person to carry out the leak rate test without any difficulty on porous load sterilizers.

6.2.15 All exposed wiring at mains voltage on the machine should be carried out with mineral insulated copper sheathed cables with overall PVC sheath, or an approved equivalent. Exposed extra low voltage wiring may be carried out in PVC cable provided it is suitably protected against mechanical damage and the effects of its environment.

6.2.16 Appendix B gives details of all instruments required to be fitted on sterilizers, and also the instruments to be used for testing, commissioning and periodically checking the accuracy of the instruments fitted on the sterilizers.

6.2.17 Where a rapid cooling device is needed, the specification should require the manufacturer to state the means by which the system may be flushed and the frequency at which such flushing operations should be carried out. Manufacturers should also be advised that it is desirable for the flushing operation to be carried out by the user without assistance from the engineering staff. On some machines, a push-button flushing cycle can be provided at a relatively small extra cost.

6.2.18 Where practicable, the jacket and all pipe work, ancillary equipment and exposed panels in the working area should be insulated to ensure a surface temperature not exceeding 60°C under continuous operating conditions with an ambient temperature of 27°C. It is desirable that the thermal insulation be easily removable and well Protected to prevent flaking during removal and replacement. Asbestos products should not be used. The insulation should have a flame rating of class 0.

6.2.19 The manufacturer should be required to provide a suitable steam pressure reducing valve or valves, with a separator on the high pressure side of each reducing valve. The vessel should be protected by means of pressure relief valves fitted to the chamber and/or jacket.

6.2.20 The manufacturer should provide an arrangement to fit a valve or cock adjacent to each steam pressure gauge on the sterilizer in a vertical position, suitable for the installation of the test gauge.

6.2.21 Any strainer in the steam, condensate, drain or water lines must be locked in a readily accessible position. Strainers in chamber drains should be properly secured.

6.2.22 Air for ballasting must be oil-free. Air for controls must be dry and clean. The sterilizer manufacturer must fit any air dryer, oil eliminator and filter on the machine in a position where it can readily be serviced.

6.2.23 Steam and condensate pipe work on the sterilizer should be arranged so as to exclude, as far as practicable, any deadlegs or pockets in which water can be retained when the machine is not in use. On fluids sterilizers, all condensate pipework and water circulating systems should be self draining; alternative means of draining must be provided where this is impractical.

6.2.24 The manufacturer should be informed that after installation, each sterilizer will be submitted to a series of tests including functional acceptance tests. These tests may have to be deferred for considerable time after the sterilizer is installed. The required tests should be set out in details in the specification. Whenever it is feasible to do so, there should be a clear statement of the date when it is expected that they shall be witnessed for the purchaser, and of the date by which all services shall be available, so that the contractor is well aware of his responsibilities and can provide accordingly in his offer.

7. INSTALLATION

7.1 General

7.1.1 Sterilizers should be sited and installed after careful planning when the problems associated with access for installation and removal, floor loading, provision of steam and other services, maintenance and ventilation have been fully examined. The sterilizer engineer should be consulted throughout the planning and purchasing stages.

7.1.2 Where the sterilizer is built-in, provision should be made for maintenance staff to gain access to the maintenance area without having to enter the sterilizing room. Provision should also be made for convenient access from the maintenance area to the front panel of the sterilizer.

7.1.3 When a sterilizer with a door at each end is installed, arrangements for maintenance should as far as possible, be for main access from the unsterile 'dirty' end, but adequate access will be necessary to both sides of the sterilizer.

7.1.4 Most machines do not require special foundations. Careful attention must be paid to height adjustment, specially where several machines are to be served by a common loading carriage system, and also to effective drainage from chamber and jacket. Attention must be paid to the noise attenuation problem when the foundations are designed (*see* 5). Attention should be drawn to the thickness of fascia panel and to any obstructions which will interfere with the loading carriage, etc. An excessively thick recess wall may be a hindrance to the maintenance work.

7.1.5 The adverse effects of excessive heat on electronic, electrical and pneumatic systems and the instruments are emphasized (see 6.1.4).

7.1.6 The engineering services to sterilizers should be provided by others and terminated within the plant room by valves and isolators normally within 2 m of the sterilizer, the size and location of the terminations having been previously agreed with the sterilizer engineer. This will allow the contract with the sterilizer manufacturer to include only the supply, delivery, offloading and transportation on site, installation, testing and commissioning of the sterilizer within the plant room.

7.2 Ventilation

7.2.1 Careful attention must be paid to the ventilation of sterilizing room and the maintenance area and the obvious advantage of a location with an outside wall should not be overlooked. The rate of air change required for this purpose must be related to the heat loss from the plant as well as to the vapour produced in and around it. The high temperature and humidity in the vicinity of the sterilizers will produce uncomfortable working conditions and may have an adverse effect on some types of automatic control equip ment. The ambient temperature in the plant room, with all plants running normally, should not be allowed to exceed 60°C under the worst summer conditions.

7.2.2 Excessive water vapour discharging from the chamber into the sterilizing room when the door is opened, should be collected at high level and exhausted to the outside.

7.2.3 Current experience indicates that a 400-600 litre sterilizer with the door closed, will release approximately 0·5 kW into the sterilizing room by radiation and convection from the machine and 3·5 kW into the maintenance area. Where sliding door machines are mounted behind a fascia panel, almost all this heat is released into the maintenance area. With the door open, additional heat into the user space might typically be 2 5 kW for a side hinged door and 1·5 kW for a sliding door.

7.3 **Steam Service**

7.3.1 Arrangements should be made for the steam service system to be thoroughly examined and for any defects to be remedied before a sterilizer is put into service. Further notes on this subject are in Appendix A. A pressure gauge should be fitted on the service main in the plant room or an equivalent place.

7.3.2 It must be emphasized that a continuous supply of steam with a dryness fraction of approximately 0·9 and at a pressure of 3·5/4·0 bar is required if steam sterilizers are to operate correctly. There is evidence that excessive fluctuation of steam pressure is more common than is generally supposed.

7.3.3 The design of steam supply pipework should be checked to ensure that it is capable of meeting the maximum steam demand for short periods with a fall in pressure not exceeding 10 percent before the final reducing valve. The effect of nearby connected equipment, such as laundry equipment, on steam demand and steam pressure should be carefully considered.

7.3.4 A connection must be provided on the steam supply line adjacent to the sterilizer to enable steam to be sampled for the presence of non-condensable gases.

7.3.5 The steam supply to sterilizer should terminate in the plant room in a header which should be adequately vented and trapped. The vent should be a separate item having a cooling pot; it should be installed on the manifold, upstream of any steam supply to individual sterilizers. The header should be of generous proportions, for example, for an installation comprising two 0·6 m^3 sterilizers, a 150 mm nominal base header running along the entire length of the plant room, that is, about 4·3 m, has proved successful.

7.3.6 It is usually impractical in the hospitals to generate the steam of requisite dryness, pressure and peak flow capacity for sterilizing from a high pressure hot water installation.

7.4 **Steam Separator and Pressure Reducing Valve**

7.4.1 The quality of steam is of vital importance to the performance of any sterilizer. Wet

steam is one of the causes of wet loads in porous load sterilizers. Superheated steam cannot be relied upon for sterilization.

7.4.2 There is no completely reliable method of measuring the dryness fraction of steam in most sterilizer installations. It is a good practice to install a separator of known efficiency, upstream of the pressure reducing valve or valves at the sterilizer.

7.4.3 If the sterilizer is to be located very near a boiler or high pressure main, it may be necessary to take special steps to prevent superheating of the steam arising from the pressure reduction.

7.4.4 The manufacturer is responsible for supplying the separator (where required) and pressure reducing valve for the machine. Pressure reducing valves for sterilizers need very careful selection. The advice of the sterilizer maker and the sterilizer engineer should be sought before any new type of pressure reducing valve is fitted to an existing sterilizer.

7.5 **Safety Valves —** Careful attention must be paid to the location of all safety valves to ensure that effective protection is afforded to both the chamber and the jacket, regardless of the closure of any associated control valve. The safety valve and discharge pipe should be of a size sufficient to prevent an increase in pressure of more than 10 percent in the chamber and jacket. Any rising discharge pipe must be fitted with a drain at the lowest point. The discharge pipe must terminate in a safe visible position not affected by frost, Any external discharge should be provided with a tell tale terminating inside the plant room.

7.6 **Water Supply**

7.6.1 An adequate supply of main water is required; it is not necessary for this to be purified or sterile but hardness fraction has to be indicated for installation of suitable water softeners. On all new installations, the supply must be taken to one or more break tanks on the sterilizer to prevent back siphonage, and not directly to any other component. These break tanks will usually have a ball valve fitted in inlet pipe and the water level must be (a) not less than 45 mm for tanks up to 4 600 litres capacity, and (b) not less than 75 mm for tanks exceeding that capacity. The overflow pipe diameter must be twice the inlet diameter or 32 mm diameter whichever is greater, and the highest level of water must be not less than 25 mm below the bottom of the overflow. The distance between the bottom of the valve inlet pipe and the bottom of the overflow pipe must not be less than the diameter of the overflow pipe. On existing installations, the supply required for ejectors, vacuum pumps, condensers and heat exchangers of all types should be taken from a break tank for the machines. All break tanks should be covered, easily cleaned and suitably vented. Automatically operated valves should be of the non-percussive type. On large installations, secondary re-circulating water cooling systems should be considered. Groups of sterilizers could be served by a common tank or tanks, provided that appropriate cleaning arrangements can be made.

7.6.2 For optimum performance, the water supplied to water ring pumps, condensers and heat exchangers should be at a temperature below 15°C. Considerable economy in water may be secured by recycling the water through cooling towers. The performance of water ring pumps, condensers and heat exchangers will also deteriorate if the water is very hard or contains large quantities of solids in suspension; this problem can be overcome by installation of simple water treatment plant at the sterilizer site.

7.7 **Compressed Air Supply —** A compressed air supply may be required. A pressure gauge should be fitted on the compressed air supply mains in the plant room. If a mains supply is used, the manufacturer must provide a drier, oil eliminator and a filter required for the sterilizer (see 6.2.22).

7.8 **Steam or Air Supplies for Door Seals —** Where a sterilizer incorporates a door seal which is either pneumatically operated or steam-operated, the pressure required is in excess of the chamber pressure and, for practical purposes, is of the order of 3·4 bar. A suitable supply for door seal service should be provided. This service must be protected by a separate safety valve.

7.9 **Drainage**

7.9.1 Condensate from the chamber may be contaminated and unsuitable for recovery, and it must pass via a clear air break into a tundish or tank which should discharge by gravity into a suitable trapped foul drain of adequate size and capacity (except as in 7.9.2). The air break in the tundish or tank must be preserved at all times so that the sterilizer and its associated piping cannot be contaminated by the foul drainage system (that is, the discharge rate from the tundish under all working conditions should be such that the maximum flow rate of effluent from the sterilizer will not cause the water level in the tundish to rise sufficiently to reach the outlet end of the sterilizer effluent pipe, thus eliminating the air break). Where a tank supplies water to a water ring vacuum pump or a water pump used for water ejector vacuum system, the overflow discharge from the tank must include an air break.

7.9.2 The advice of the consultant microbiologist should be sought where a bacteriological hazard is likely to arise. A sealed break tank in lieu of a tundish may be required for each sterilizer. This should be vented to the outside of the building and the vent should terminate above

roof level clear of any ventilation inlet, window, etc. A trap should be provided between the break tank and the connection to the drainage system. These arrangements will be required where the sterilizer is to be used for processing bacteriologically hazardous material which has to be made safe, for example, in certain laboratory applications. STERILIZERS USED IN THE PRODUCTION OF STERILE PRODUCTS FOR EITHER PHARMACEUTICAL OR CLINICAL USE SHOULD NO Γ EMPLOY THIS TYPE OF DRAINAGE SYSTEM. The consultant microbiologist must be consulted on this subject about all sterilizers for any high security infectious diseases unit.

7.9.3 Condensate from jacket, steam separator and other trapping points on the steam pipework may be recovered when it is convenient and economic to do this.

7.9.4 Means should be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical items. Tundishes should be appropriately shaped and sited. The use of plastic drainage pipework may be inappropriate because of discharge of hot water.

7.10 Pipework Arrangements

7.10.1 All steam pipework shall be designed in such a way so that any condensate flows by gravity in the same direction as the steam. This general principle applies equally to steam mains, branch connections and pipework on the sterilizer itself. Care should be taken to trap and drain any condensate which may be collected in pockets in the pipework or the sterilizers. Deadlegs should be avoided.

7.10.2 Care should be taken to ensure that sterilizers are connected to mains services which are of adequate capacity and otherwise suitable for the sterilizer load requirements. Inadequate services may cause malfunctioning; for example, compressed air operated valves or door seals may fail if the pressure fluctuates.

7.11 Commissioning Procedure

7.11.1 The process of setting sterilizers into full working order should be undertaken by the contractor in accordance with the instructions set out in the contract documents. It will be necessary for him to provide test instruments and equipment and to perform the tests and demonstrations which are required before the installation can be accepted for use in accordance with the contract, to the satisfaction of the contract supervising officer (CSO), or someone appointed by him to act on his behalf in this matter. The hospital will provide the load. The various checks and tests are referred to in Appendix E and summarized in Appendix F. The most important individual tests are described in detail in other appendices. The sterilizer engineer should be nominated either as the CSO or nominated to act on his behalf.

7.11.2 The contractor must satisfy the CSO that the accuracy and condition of his instruments and equipment meet the requirements for test instruments specified in B-7.1.1 in the sequence listed and that they have been calibrated on site as described therein.

7.11.3 Commissioning is process in which work is completed on site in the following order by the contractor or contractors:

a) Demonstration of adequacy of services;

b) Demonstration of general engineering performance of the sterilizer;

c) Testing of mechanical and electrical functions of the sterilizer, including the safety devices; and

d) Testing of specific sterilizing performance for the class of the sterilizer (see Appendices G to N).

These procedures should be witnessed by the sterilizer engineer. Some guidance on procedures (b) and (c) is given in Appendix E but it is not exhaustive and does not cover every case. The contractor shall not be responsible, unless otherwise specified, for tests to establish Master Temperature Records (MTRs) for production control purposes.

7.11.4 On satisfactory completion of the work as in 7.11.3, the sterilizer engineer should carry out further tests on the sterilizers, as necessary, to obtain initial performance data for the use of the engineer. He should also establish MTRs for sterilizers processing medicinal products and for hot air sterilizers.

7.11.5 Arrangements should be made to ensure that all staff concerned with the operation and maintenance of the sterilizer have ready access to manufacturer's instructions, service manuals and the data recorded during commissioning. Maintenance and operating procedure is covered extensively in Appendix D. The importance and subsequent use of records taken during commissioning is also referred to in Appendix D.

8. TESTING OF STERILIZERS

8.1 Normal Test Procedures

8.1.1 The instruments required for testing sterilizers are described in Appendix B. The frequencies at which tests should be undertaken in a routine manner are set out in the table of sterilizer performance tests in Appendix F.

8.1.2 In addition, tests will be required following certain maintenance work which may be either scheduled or unscheduled, as described in the notes accompanying the table in Appendix F.

8.1.3 The tests are as follows:

a) Performance tests for porous load sterilizers (see Appendix G),

b) Bowie/Dick tape test for porous load sterilizers (see Appendix H),

c) Leak rate test for porous load sterilizers (see Appendix J),

d) Air detector performance test for porous load sterilizers (see Appendix K),

e) Performance tests for fluids sterilizers (see Adpendix L),

f) Performance tests for unwrapped instruments and utensils sterilizers (see Appendix M), and

g) Performance tests for hot air sterilizers (see Appendix N).

8.2 **Non-standard Test Procedures** — The use of spore tests or chemical test devices (other than Bowie/Dick tape test for porous load sterilizers) for routine testing of positive pressure steam sterilizers and hot air sterilizers is not recommended. Where the attainment of sterilizing conditions cannot be confirmed by measurement of physical parameters, the advice of the responsible microbiologist should be sought in evaluating a sterilizing process.

9. PROCEDURE FOR DEALING WITH DEFECTIVE STERILIZERS AND REPORTING THE ACCIDENTS

9.1 General

9.1.1 No attempt should be made to open a chamber door under 'fault' conditions by defeating the door interlock unless:

a) The chamber is at atmospheric pressure, and

b) Any fluids in the fluid containers are at a temperature below 70°C.

In case of (b) above, the fluid containers should be allowed to cool naturally overnight.

9.1.2 Reference should be made to Appendix D, which sets out the responsibilities of various parties involved and includes sections on fault procedures, recording of faults and the plant history record.

9.2 **Reporting of Defects** — The importance of prompt reporting and recording of all faults or abnormalities is emphasised. When complaints about performance have arisen, it has often been found that known faults have not been recorded and reported to the engineer. Failure to report and/or withdraw machines from service, following difficulty or abnormality affecting doors on their closing and locking mechanisms has resulted in serious accidents.

9.3 Reporting and Recording the Accidents — Accidents in which anyone is injured or could have been injured are reportable under the Industrial Safety Act and must be recorded in the accident record book.

9.4 **Reporting to Department** — The types of occurrence which should be reported are those where some central action may be helpful in bringing about necessary improvements in the standards of sefety, construction, performance, reliability or economics of sterilizers and would include, for example:

a) Accidents involving sterilizers;

b) Failures of integrity of pressure level, that is, failures of door mechanisms, explosions and bursting or cracking of parts of the chamber, door, jacket or structural members;

c) Incipient or potential defects likely to lead to failures as at (b) above;

d) Failure of basic safety devices connected with closing/opening of the door and pressurization of the chamber;

e) Failure of electrical safety;

f) Constructional features which do not comply with safety codes or with accepted good practice or are hazardous in some way;

g) Unusual circumstances which may jeopardize safety or proper functioning, for example, if safety devices or automatic process controls can be defeated under certain conditions;

h) Inability of properly maintained and operated machine to meet the performance standards specified for it; and

j) Unreliability, persistent malfunctioning, frequent failures of particular components or any other feature which generates excessive and/or abnormally expensive maintenance or operational requirements, having regard to the intensity of use and operating conditions.

10. MAINTENANCE, OPERATION POLICY AND PROCEDURE

10.1 General

10.1.1 Planned maintenance arrangements should be made for sterilizers as soon as possible. Arrangements for proper maintenance of all sterilizing equipment should be made by concerned authorities. The maintenance and testing of sterilizers are specialized functions.

10.1.2 Reference should be made to Appendix D, which sets out the responsibilities and procedures involved and emphasizes the need for close co-operation between the sterilizer engineer and the operators.

10.13 The engineer should have the necessary testing facilities to monitor sterilizer performace by fully instrumented tests.

10.1.4 Attention is drawn to advice and assistance available from the following sources:

a) Manufacturers, and

b) The appropriate authorities in the country.

10.2 **Maintenance and Testing Philosophy**

10.2.1 The philosophy on maintenance and testing embodies three main principles to ensure that adequate standards of performance and safety are attained and sustained. These are as follows:

a) That all sterilizers are subjected to a carefully planned programme of tests to monitor their performance (see Appendix F), and

b) That all sterilizers are subjected to a programme of planned preventive maintenance (PPM) under the control of the engineer, irrespective of whether or not a planned preventive maintenance scheme is being operated in the hospital generally.

10.2.2 The scheduled test programme includes simple testing methods undertaken by the operator as well as the more complicated tests undertaken by the sterilizer engineer. The test programme fulfils the objectives set out in Appendix D by demonstrating whether or not the equipment is functioning satisfactorily.

10.2.3 The maintenance philosophy has the following requirements:

a) All parts of the sterilizer which are vital to correct functioning and/or safety must be tested at least weekly. This is interpreted thus:

i) There is no need to test components individually in those cases where any malfunction will be revealed by the sterilizer performance tests prescribed for weekly or more frequent intervals; and

ii) Where correct functioning of particularly important components is not necessarily verified by the performance tests prescribed for the sterilizer at least weekly, those components must be individually tested each week and reference to testing them must be included in the schedules of maintenance tasks. This applies, for example, to some door interlocks which may only be required to perform their safety function when presented with an abnormal condition.

b) The maintenance routines should include those tasks such as lubrication and occasional dismantling of particular components, such as pumps, the need for which, at appropriate intervals, is indicated by normal good practice, manufacturer's advice and experience. Apart from those tasks, the maintenance routines should concentrate on verifying the condition of the sterilizer and its components by means of testing and examination without dismantling, such as parts which are working well should be left alone and not disturbed unnecessarily.

10.3 **Plant History Record and Sterilizer Processing Log** — A plant history record must be kept for every sterilizer and that a processing log book must also be kept for sterilizer processing medicinal substances and for porous load sterilizers (see D-7.1).

10.4 Routine Cleaning and Preparation — The operational duties to be carried out by the operator should be recorded in a written form, and the procedures include those mentioned below:

a) It will not usually be necessary to clean the chambers of porous load sterilizers daily, but each day the interior of the chamber of other machines, including trays and shelves, should be wiped down with a clean damp cloth. Cleaning is specially important for fluids sterilizers dealing with saline solutions. The use of abrasives or cleaning materials which leave deposits must be avoided. A mild detergent may sometimes be used, followed by a clean water rinse. A detergent cleaning procedure must not be adopted on fluids sterilizers which use rapid coolers of the 'condensate-collecting' type. On such machines, the chamber, etc, should be wiped down and cleaned in accordance with the manufacturer's instructions.

b) The grating in the opening to the chamber discharge line should be cleaned daily, or more often if necessary. This can normally be done by the operator where it is readily accessible, or otherwise by the maintenance engineer's staff.

c) The door seal should be wiped clean each day with a damp cloth and inspected for damage. This can normally be done by the operator if the seal is completely exposed when the door is open, though the inspection will then be a cursory one. Where access is difficult, it should be done by the engineer.

d) Attention must be paid to the requirements that certain instrument readings are to be recorded at the commencement of the day (see D-8.8.3). Any deviation from normal should be reported and investigated before the work proceeds.

e) On many fluid sterilizers fitted with rapid cooling, the chamber condensate is collected for use as the coolant; if a container fails the contents will, therefore, flow into the coolant pipework and tank The condensate should be dumped at the end of each cycle, If it is not dumped, some solutions, particularly saline, may cause serious damage to the sterilizer. For this reason, the cooling system of such machines should be flushed after such leakage has occurred; the system should in any case be flushed periodically (usually weekly) as part of the PPM routines carried out by the engineer. For this purpose, it may, in some cases, be necessary to open a drain plug in the storage tank.

10.5 Temperature Recorders and Record Charts

10.5.1 A temperature recorder should be treated as a valuable instrument to monitor general functioning and performance of a sterilizer. Temperatures read from a recorder should, however, be regarded with caution and interpreted only in the light of previous records and tests, and knowledge of the characteristics of the particular sterilizers / load / recorder combination and the position from which the recorder senses. Temperature sensing and measuring instruments (specially recorders) are subject both to inherent calibration errors and to loss of calibration with use. No batch of sterile fluids or load processed by a hot air sterilizer should be passed as sterile unless the temperature recorder chart (TRC) is satisfactory when compared with the corresponding MTRs, and any abnormal trace should be reported to the maintenance engineer.

10.5.2 A recorder should not be interfered with more than is absolutely necessary whilst it is working correctly. The manufacturer's instructions on operation and adjustment must be strictly adhered to. Maintenance of these instruments demands specialized attention and is best undertaken by the manufacturer.

10.5.3 All persons who may need to change charts and/or replenish ink supplies on recorders during the course of their duties should be properly instructed so that they appreciate the delicate nature of these instruments, and effectively trained in the performance of these duties.

10.5.4 The instrument case should never be left open; broken glass should be replaced promptly.

10.5.5 The preparation and use of MTRs and TRCs and the vital role these play in the management and control of sterile material production is set out in Appendix D. The special importance of recorder charts in the quality assurance documentation associated with the production of sterile aqueous fluids and other medicinal substances should be described in a document form.

10.6 Maintenance — Staff and Training

10.6.1 It is most important that staff at all levels whose duties include responsibilities for the maintenance of sterilizers have a sound general knowledgde of the principles, design and functions of sterilizers. They must be thoroughly instructed and familiar with those types and models of machine with which they are directly concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, the safety of others and general safety. In particular, the engineer should be fully conversant with all the machines for which he is responsible. There will usually be some routine tasks which have to be done by hospital staff, even if maintenance is normally carried out under contract. In addition, the engineer must be in a position to be able to deal with any breakdown in an emergency. He should also have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by his staff. He must be competent to supervise and monitor work carried out either by hospital staff or under contract, and to conduct quarterly and half-yearly tests (see Appendix F).

10.6.2 Detailed instruction about particular sterilizer models is usually best obtained from the manufacturers, either on site, for example, during commissioning, or by courses at their works.

10.7 Planned Preventive Maintenance (PPM)

10.7.1 A suitable system of planned preventive engineering maintenance should be followed.

10.7.2 The PPM programme supplied by the manufacturers should be used for all new sterilizers. For existing sterilizers, the manufacturer's recommeded PPM programme should be used wherever it is available.

10.7.3 The schedules must be adopted, after taking manufacturer's advice, wherever possible, to suit each particular sterilizer and the prevailing conditions. The PPM frequencies in most manufacturer's schedules, are based on an average intensity of use, typically that of a sterilizer in a CSSD or TSSU working on a normal single shift basis If the intensity of use differs significantly from that, some of the frequencies may need to be adjusted accordingly; in any case, frequencies should be kept under review in the light of operational experience. It is important to ensure that sterilizer maintenance work is pre-planned as much as possible to fit in with the production schedules.

10.7.4 Although the manufacturer is required to carry out certain inspection and maintenance procedures under the terms of his guarantee, it is essential that engineering staff undertake the PPM programme at all times, including the guarantee period, unless otherwise stipulated in the contract. The engineer must also implement any further reasonable instructions given by the manufacturer during the period of the guarantee. Failure to do this may involve the manufacturer an additional expense for which he may seek reimbursement and it might also jeopardize the protection afforded by the manufacturer's guarantee.

10.7.5 Before commencing the weekly tasks, the maintenance engineer should satisfy himself that the daily tasks have been carried out by the operator on the lines indicated in air elimination tests from the chamber and load, and that any approved routine tests, Bowie / Dick tape test, and air elimination tests from the chamber and load have been carried out and the results properly recorded by the operator. If he is not satisfied, he should record his dissatisfaction in detail in sterilizer processing log, or in plant history record where a processing log is not required, and draw the attention of the operator to the matter.

10.8 **Overhauls** — The engineer should arrange for each sterilizer to receive -a thorough overhaul every two years. This should be arranged to coincide with the statutory inspection by insurance company's engineer surveyor. The overhauls and inspections should be staggered in the maintenance programme so that in any particular installation, only one machine at a time need be withdrawn from service. Arrangements should be made for assistance from another department and / or for overtime working if the need for standby capacity arises during normal overhauls.

10.9 Calibration of Instruments Fitted to Sterilizer — Every three months, or more frequently, if considered necessary, the accuracy of the gauges and the thermometers should be ascertained by the engineer. Any instrument which is found to read seriously in error or which is inconsistent, that is, will not repeat satisfactorily, must be discarded, or repaired by the makers if that is practical and economic. Instruments which do repeat satisfactorily but read slightly in error should be dealt with as follows:

a) Instruments fitted with pointer adjustment facility should be adjusted to read correctly at the normal working temperature or pressure, and

b) If the instrument has no provision for pointer adjustment, it should be replaced as soon as possible by the engineer and the operator should be advised accordingly.

10.10 Air-Tightness of Chamber

10.10.1 Air-tightness of the chamber is of fundamental importance to the correct functioning of all sterilizers. The effectiveness of door seal is the chief factor in air-tightness of the chamber as a whole and it must receive particularly careful attention as advised by the manufacturer. The working life of door seals varies widely, but it is essential that all seals are renewed regularly at the intervals recommended by the manufacturer. Seals must also be renewed when there is any evidence of damage or deterioration.

10.10.2 Although the door seal is the major potential source of air leakage into the chamber, there are many other points at which leakage is liable to occur; these include joints in pipework, connections to gauges, blanked off connections for test gauges, thermocouple entry points (both when in use and when blanked off), glands or seats of various valves and door safety interlocks. Pipework joints and connections to the chamber sometimes develop leaks after a period in service, probably due to slight loosening caused by the repeated stress reversals associated with alternating pressure and vacuum conditions, specially where compression fittings have been used. Occasionally, air leakage into the chamber may be the first recognized symptom of cracks developing in the chamber welds or platework.

10.11 Air Detection Devices on Porous Load Sterilizers

10.11.1 A leak in an air detection device might be so small that it would be unnoticed by the ordinary leak rate test but such a small leak would have a very serious effect in most machines since it would permit the expulsion by steam of any air present in the device, This would indicate falsely that all air had been removed from the chamber. With certain designs of air detector, the reverse may also be true and a leak may cause the air detector to reject every load.

10.11.2 Particular care must be taken when installing, removing or adjusting any part of this device. It is preferable not to interfere with it except when necessary. The routine procedure to be adopted for determining the sensitivity of the detector is normally as stated by the manufacturer (see *also* Appendix K).

10.12 Stainless Steel Chambers — Stainless steel is used in the manufacture of many chambers and these may be of solid stainless steel or of stainless steel clad mild steel. Over a wide variation in specification, stainless steel are susceptible to crevice corrosion and stress corrosion cracking, initiated by chemical attack. These phenomena occur when the material is subjected to a combination of stress, heat and contact with chemicals, notable chlorides or strong alkalis. Damage is likely to occur when these factors are acting together, even though they are at levels far below

anything which would be of significance taken separately. The first two factors, stress and heat, are necessarily present in all steam sterilizers. The third factor, chemical contact, may also be present in sterilizers under the following circumstances:

a) In sterilizers processing certain fluids, a spillage, for example, by breakage of a bottle of saline solution, will introduce chloride salts into the chamber;

b) In small electrically heated sterilizers where steam is generated within the chamber by an immersion heater, a build-up of both alkalis and chloride salts may occur if these machines are supplied with tap water;

c) If there is excessive carry over of boiler water with the steam, this is likely to include significant concentrations of both alkalis and chloride salts; and

d) In addition to the risks of stress corrosion cracking, cases have occurred in certain parts of the country where the use of tap water in electrically heated bench top sterilizers has resulted in severe pitting corrosion leading to perforation of the chamber (*see* 3.4).

Both crevice corrosion and stress corrosion cracking can largely be prevented by correct operational procedures together, where appropriate, with regular cleaning and light hand polishing of the chamber to remove microscopic initiating sites. It is particularly important to ensure that the stainless steel chambers of fluids sterilizers are polished at quarterly intervals, and that the cooling systems are flushed as required in 10.4 (e). Manual use of iron free abrasives should be employed for polishing. Conventional engineering abrasives, such as, fine emery and Carborundum may be used. Household or domestic scouring and polishing compounds must not be used since they often contain chlorine or other corrosive agents and might thus cause, rather than prevent, trouble. The manufacturer's advice should be followed and care taken not to damage the door seal. Precautions must be taken to prevent the entry of foreign matter into the chamber drain during polishing and cleaning; the drain should be disconnected while the work is in progress and the chamber should be thoroughly flushed out before the drain is re-connected.

10.13 Maintenance of Ancillary **Equipment**— Because of wide variation in design of devices performing similar duties, manufacturer's instructions should be consulted about maintenance and operation of these items.

18.14 Steam Generators

10.14.1 Local steam generators, whether provided separately or as an integral part of a sterilizer, are steam boilers and they must be recognized and treated as such. Although they are equipped for automatic operation, they must receive regular supervision such as would be accorded to any other automatic steam boiler plant. It is not acceptable for them to be left unattended for more than 24 hours; they must be looked at by a competent boiler attendant or engineer at least daily whilst in use and in many cases, more frequently. They are notoriously liable to trouble from scale formation.

10.14.2 The amount and frequency of attention necessary in each case will depend largely on the nature of the water supply, water treatment arrangements and the intensity of use. Because there is often little or no condensate returned to these steam generators, their feed water is usually almost 100 percent 'make-up', and as a result, the concentrations of dissolved and suspended solids in the boiler water build up quickly to very high levels. It is essential that an effective blowing-down regime be established, and adhered to, in order to contain the concentration of dissolved and suspended solids in the boiler water within acceptable limits. The advice of the manufacturer about water supply, water treatment, blowing-down and other operational practices should be strictly observed (see *also* Appendix A).

10.14.3 Attention to water quality inside the generator is specially important if, as is often the case, the generator vessel is of stainless steel since this may be subject to the same risk of stress corrosion cracking encountered in stainless steel sterilizer chambers.

10.14.4 Failure to provide adequate supervision, with consequential inadequate control of water quality including insufficient blowing-down, have resulted in such severe corrosion of steam generators that in some cases, internal parts have collapsed and the safety of operators has been seriously jeopardized.

10.15 Return of Sterilizers to Service after Maintenance

10.15.1 Whenever any maintenance work, either scheduled or unscheduled, has been carried out on a sterilizer, it should not be returned to service unit1 the following requirements have been satisfied:

aj It has passed functional tests appropriately to its type and the particular circumstances (see Appendix F), and

b) In certain circumstances [see D-8.6.3(a) to (h)], the sterilizer engineer is also satisfied that it is functioning correctly.

10.15.2 In every case, the tests to be applied will include running the machine through a full cycle under automatic control, with a standard load, whilst significant cycle parameters (such as temperature, pressure and time) are logged and checked against the normal values for that machine [see D-4.4 and D-8.2.1 (a)]. Other tests will also be involved, including approved standard tests such as the Bowie/Dick tape test and the leak rate test, where relevant, and on some occasions fully instrumented tests using multi-channel thermocouple recorders will be required.

11. HOT AIR STERILIZERS

11.1 Introduction

11.1.1 Hot air sterilizing is an accepted method for those loads into which the steam cannot readily penetrate, such as assembled syringes, pneumatically operated and multiple wide pointed instruments and for non-aqueous products, such as oils and powders.

11.1.2 In steam sterilizers, the heating of the contents is effectively achieved by latent heat transfer whereas hot air sterilizers rely on sensible heat transfer only. Even temperature distribution throughout the chamber and load is essential, and this is best achieved in hot air sterilizers by forced air circulation, that is, by means of a fan.

11.1.3 Most existing hot air sterilizers are not equipped with safety devices and automatic cycle controls usually associated with steam sterilizers, and most are at present manually operated. It is essential, therefore, that their use is controlled by responsible persons who are adequately trained.

11.1.4 The time/ temperature relationships normally used are as follows:

160°C for 60 minutes	
170°C for 40 minutes	
180°C for 20 minutes	
Additionally, for certain pharmaceutical products	150°C for 60 minutes

NOTE - The items to be sterilized must be held at the stated temperature for at least the time given above, heating up and cooling down times are additional.

11.2 Recommendations in respect of Hot Air Sterilizers for the Health Service.

11.2.1 Sterilizers should conform to IS : 3119-1978*.

11.2.2 A hot air sterilizer is not suitable for use as a drying cabinet.

11.2.3 Suitable thermocouple entry ports should be provided.

11.2.4 Automatic process control is desirable and should be introduced. All new sterilizers should be automatically controlled.

*Specification for hot air sterilizers (*first revision*).

11.2.5 The door must be capable of being locked. It is preferable that the locking system be automatic as in **11.4.3** and 11.4.4. Alternatively, a simple key-operated lock for control by the operator is acceptable.

11.3 Instrumentation and Process Control

11.3.1 Instrumentation (which should include a chart recorder and indicating thermometer) required for hot air sterilizers is referred to in Appendix B. The sensors for indicating thermometer and temperature recorder should be permanently fixed. The thermometer and recorder may show different temperatures because the sensing elements may be located separately but their sensors should be sited in positions which will minimize this difference.

11.3.2 An overheat cut-out should be fitted to all hot air sterilizers (see 11.4.2).

11.3.3 Although fully automatic controls with full stage indication are desirable on all sterilizers, and essential on new sterilizers; where these cannot be provided, the following table indicates those features considered either essential or desirable for effective manual control.

Item	*Feature*	*Essential*	*Desirable*
a) *Controls*			
1.	Push button or starting switch for process, separate from mains isolating switch	*Yes*	
2.	Manually adjustable process timer (O-6 hours)	**Yes**	
3.	Sterilizing temperature control thermostat, adjustable over the range 140-180°C	**Yes**	
4.	Overheat cut-out, adjustable up to but not exceeding 200°C, with manual reset facility	**Yes**	
5.	Independent adjustable thermostat (0-100°C) to permit fan to continue to run after sterilizing stage until load temperature has fallen to preselected temperature (normally around 60°C)		**Yes**
b) *Stage Indicators*			
6.	Electricity supply switched on	**Yes**	
7.	Chamber heaters energized	**Yes**	
8.	Fan run-on timer operating	**Yes** (if applicable)	
9.	Process complete	Yes	
10.	Fault condition		Yes
11.	Door release		Yes
12.	Three digit process counter	**Yes**	

11.3.4 Adjustment of timers and the sterilizing temperature thermostats should either require the use of tools or the controls which should be protected against inadvertent adjustment; the settings should, however, be visible to the user. The reset button for the chamber over-heat cut-out and the door release over-ride should be similarly protected; alternatively, key switches may be used.

Il.4 Safety **Features Required**

11.4.1 All controls should be designed to fail safe, wherever practicable.

11.4.2 A manually re-settable, non-self resetting overhead cut-out, set to operate at a temperature not exceeding 200°C, should be fitted to all hot air sterilizers.

11.4.3 The door should be interlocked so that the operating cycle can neither be started until it is closed and secured nor opened until a satisfactory sterilizing cycle has been completed, except by the use of a manual over-ride release not normally accessible to the operator.

11.4.4 A sterilizer with doors at opposite ends should have interlocks to ensure that both doors cannot be opened together, and the door at the 'unloading end can be opened only after the completion of a satisfactory sterilizing cycle.

11.4.5 If the electricity supply is interrupted before a cycle is completed, the process timer should automatically reset to zero and require manual reset. Restoration of electrical supply should be signalled by the fault indicator, but there should be no automatic re-starting of the process.

11.5 Use of Hot Air Sterilizers

11.5.1 Users must ensure that the selected process time is that stated on the MTR as defined in Appendices N and P. In addition, the batch type and size, loading **pattern** and shelving system must be in accordance with the information stated on the MTR.

11.5.2 The process time is the sum of:

a) Time taken for the free chamber space to achieve the temperature,

b) Time required for all parts of the load to reach the temperature, and

c) The sterilizing time.

NOTE — If a separate cooling thermostat is fitted, the total cycle time will be longer, that is, the processing time plus the cooling time.

11.5.3 Variation from established loading pattern may seriously affect the heat distribution in the chamber and sterilization may, therefore, not be achieved throughout the load.

11.5.4 Consideration should be given to the provision of either purpose-made shelving, or spacers, for accurate and repeatable positioning of specific load items, so that the loading pattern **used** for the preparation of the MTR is repeated in production loads.

11.5.5 The chamber should not be over-filled.

11.5.6 Good thermal contact is desirable between load items and their containers. In the case of particular heavy instruments, it is desirable to support the instrument by a metal cradle within its container to assist heat transference by conduction and thus avoid an excessively long time for the whole load to reach the sterilizing.

11.5.7 Improved heat transfer can be obtained by wrapping the items in an aluminium foil. This may be preferable to wrapping them in paper, or enclosing them in glass tubes or metal containers.

APPENDIX A

[Clauses 2.1, 6.1.3.1(a), 7.3.1, 10.14.2, G-4.3, H-7.5 *and* M-4.3]

STEAM QUALITY

A-l. GENERAL

A-l.1 The requirements given below apply mainly to steam supplies for porous load sterilizers and sterilizers for instruments and utensils.

A-1.2 The pre-requisite for efficient steam sterilizer performance is a steam supply of suitable quality. Problems are unlikely to occur if the dryness fraction is approximately 0·9 before the final reducing valve and the pressure reduction ratio through the valve is of the order of 2 : 1.

A-l.3 Although experience has shown that acceptable conditions are sometime achieved when optimum conditions do not prevail, significant deviations are likely to cause the following problems:

a) Wet loads, resulting from too low a dryness fraction;

b) Difficulties with reducing valve operation, resulting from too low pressure reduction ratio; and

c) Superheating, resulting from either too high a dryness fraction before the reducing valve, or excessive pressure reduction through the valve; superheating may be severe if both conditions are present simultaneously.

A-l.4 The steam supply to the reducing valve on the sterilizer should not be subjected to pressure fluctuations in excess of 10 percent.

A-I.5 Adequate trapping and venting of steam supply system, good installation practice to remove condensate air and non-condensable gases, and efficient thermal insulation are important if problems arising from poor steam quality are to be avoided.

A-l.6 When existing sterilizing equipment is to be replaced; it is desirable to appraise the steam supply system because the dryness fraction of the existing supply may not be appropriate for the proposed new equipment.

A-1.7 Superheating of steam in the chamber may be avoided by using two or more stages of pressure reduction. The reducing valves should be installed some distance apart, so that the normal heat losses from the pipe will sufficiently reduce the energy of the steam and expansion through each valve will not result in superheating.

A-2. WET LOAD

A-2.1 This section is directed almost entirely to problems arising with porous load sterilizers and with sterilizers for unwrapped instruments and utensils.

A-2.2 Although wet steam supplies shall usually result in wet loads, experience has shown that a high proportion of wet load problems can be attributed to improper wrapping or packing of load and improper loading ot the sterilizer, particularly when metal or other heavy objects are being processed in a porous load machine.

A-2.3 The energy which heats the load is derived almost entirely from the latent heat given, as the steam **condenses. The greater the mass of** the **individual objects in the load,** the greater is the amount of steam condensed during this heating process and the greater is the energy absorbed by each object. · The process is substantially reversible. By subjecting the chamber to vacuum during the drying stage, the lowered boiling point of water associated with the reduced pressure enable the heat energy stored in the object to be used to re-evaporate the condensate, and as a consequence the object is cooled. It is evident that the re-evaporation process will not occur if the condensate becomes separated from the object to which the latent heat has been imparted. In order to ensure dry loads, it is necessary either to retain the condensate close to the object on which it was formed during heating or to ensure that the condensate is drained clear of the load. Parts of the wrapping are likely to become saturated in certain cases, This saturation may occur at an early stage of the heating process when objects such as metal instruments having a relatively high thermal mass are sterilized. The excess condensate in these cases may migrate to other parts of the load from which it may not be evaporated; it is likely to be a particular problem when the objects are heavy. This migration of condensate may be avoided by including absorbent material, suitably positioned inside each pack and quite separate from the wrapping. The optimum amount and arrangement of this extra padding can only be determined by experiment.

A-2.4 As far as possible, loads should be arranged so that the condensate runs direcly to the drain, away from the individual objects, for example, holloware should not be processed in an upright position (holloware must, in any case, be inverted in unwrapped bowl and instrument sterilizers so that the air will be displaced). In porous load sterilizers, it may not be practicable to ensure that wrapped holloware is always processed inverted but the drainage problem may then be overcome by placing absorbent material inside the vessels.

A-2.5 Wet patches on loads may also result from condensate dripping or draining on to the load from load containers or from loading carriages of poor design. They may also result from processing tiers of instrument trays without using drip deflectors between each tier.

A-2.6 The advice of the sterilizer engineer should be obtained when all normal procedures fail to secure dry loads.

A-3. WET STEAM SUPPLY

A-3.1 Some wet loads are undoubtedly due to supply of wet steam to the sterilizers. The undermentioned are some of the causes and remedies for this situation:

a) Existing or new steam mains or manifolds which are inadequately sloped and drained. The remedy is obvious.

b) Defective and/or inefficient thermal insulation of the pipework between the boiler and the sterilizer will cause excessive condensation of the supply steam. Effective lagging is essential.

c) There must be a properly designed and correctly installed separator and steam trap set adjacent to the sterilizer.

d) The sterilizer should be connected to a live steam main, not to an inadequately drained or inadequately vented 'deadleg'. Long branch connections to sterilizers should be avoided.

e) The steam supply pipework between the mains connection and final separator should fall towards the separator, for drainage into the trap. Additional drain points and traps may be required, depending upon the piping arrangement. The accumulation of condensate in the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the steam main and the sterilizer chamber. This can be achieved by the correct inclination of each portion of pipework and by adequate trapping.

f) The steam supply to the sterilizer should be taken from the top of the main pipe.

g) 'Priming' may be occurring in the boilers. Modern compact and highly rated boilers are particularly sensitive to feed water treatment and are much more likely to prime than boilers of traditional design. Priming or foaming which results in carry-over of the boiler water, may be caused by:

1) Incorrect feed water treatment (see A-5.1 and A-5.2),

2) Forcing a boiler which needs internal cleaning, and

3) Violent boiling, under fluctuating load conditions (specially with high water levels).

A-4. NON-CONDENSABLE GASES

A-4.1 The presence of non-condensable gases in steam mains supplying sterilizers may cause the sterilizer air detector to abort cycles when a leak rate test can otherwise be satisfactorily performed. The presence of these gases may also be revealed by the Bowie/Dick tape test (the setting of the air detector should NOT be modified to compensate for this).

A-4.2 Some causes of the presence of non-condensable gases in the steam supply are as follows:

a) Boiler feed water which is not properly de-gassed or is allowed to fall below 80°C during periods of high demand (this is often due to general failure to return condensate from the hospital and is sometimes due to inadequate insulation of the condensate return pipe),

NOTE — A simple base exchange system of water treatment does not remove bicarbonate ions from the water but, in effect, exchanges the scale forming bicarbonates for sludge forming bicarbonates which can be removed by blowing down. Carbon dioxide will be liberated during heating, regardless of whether or not this form of treatment is used.

b) Inadequate venting and trapping of the steam lines,

c) Boiler feed pump glands leaking, and

d) Incorrect water inlet to feed tanks.

A-4.3 Certain boxes or trays, for example, Bripac boxes when first used, are likely to give off non-condensable gases which will cause the air detector to abort the cycle. Such material should be pre-processed separately before first being used in the normal sterilizing procedure.

A-5. WATER TREATMENT

A-5.1 The quality of steam may be greatly influenced by the boiler water treatment and a study of the treatment is essential in many cases. The study should cover the analysis of water, the facilities for venting and the blow-down regime required in order to optimize the total dissolved solids (TDS) content and ensure protection of boiler against corrosion whilst minimizing the entrainment of non-condensable gases in the steam supply. This study should be carried out by a water treatment specialist.

A-5.2 It may be necessary to re-assess the water treatment procedure for existing boilers in those cases where the steam quality indicates the need, for example, where repeated and unaccountable Bowie/Dick tape test failures, or cycle abortion by air detector system, or both have occurred. This would certainly be the case when investigation shows that the sterilizer is in good order but that the steam supply may be suspected.

A-6. SMALL STEEL GENERATORS/BODIES

A-6.1 Small local boilers and boilers constructed integrally with sterilizers are particularly susceptible to the problems of low boiler feed water temperatures, inadequate venting and trapping and incorrect water inlet to feed tanks. These problems are accentuated because the condensate from the sterilizers is not returned to the feed tank.

A-7. SUPERHEATED STEAM

A-7.1 General

A-7.1.1 Superheated steam is an unsuitable medium for moist heat sterilization (in properly designed sterilizers, moist steam at, for example, 134°C will sterilize in three minutes while dry heat at 160°C will sterilize in one hour). Superheat conditions within the load and chamber may result from:

a) Adiabatic expansion,

b) Exothermic reaction, and

c) Heating from an outside source (such as overheated jacket).

Superheating from any cause may result in failure to sterilize, scorching of textiles and paper and rapid deterioration of rubber.

A-7.1.2 Superheating due to adiabatic expansion is usually the result of an excessive reduction in pressure through a throttling device, such as a reducing valve or a partially closed main steam valve. It is unlikely to be of significance in the circumstances normally encountered in hospital steam distribution systems but it may arise if the main steam supply is unusually dry, or the pressure unusually high before the throttling device.

A-7.1.3 Practical considerations sometimes dictate the need to accent limited adiabatic superheating in the chamber provided it can' be demonstrated to be a transient condition. Specifically, the maximum superheat measured in the chamber space must not exceed 5°C and for the last two minutes of the sterilization hold time, must not exceed 2°C.

A-7.1.4 When adiabatic superheating occurs, it can sometimes be overcome by installing a second reducing valve in the steam main well upstream of the sterilizer, so that the pressure reduction ratio at the sterilizer is not greater than 2 : 1 thus permitting the heat losses from the pipework to reduce the dryness fraction upstream of the final reducing valve, whilst minimizing the effect of expansion through the reducing valve drying (but if steam is used for door seal inflation, the first reducing valve must not reduce the pressure below that required for the seal).

A-7.2 **Exothermic Superheating**

A-7.2.1 Superheating arising from exothermic reaction may occur during sterilizing as a result of dehydration of exceptionally dry material. In these circumstances, the superheat condition is not necessarily transient; it may be severe and may persist for the entire sterilization hold time, with consequential risk of a failure to sterilize. This phenomenon is usually associated with certain textiles, particularly those incorporating cotton which have become excessively dry before sterilization. It may occur at any time when the ambient humidity is unusually low. It is generally revealed by thermocouple testing but only if the material used for the test pack has been exposed to the same environmental conditions as the production material.

A-7.2.2 It is unlikely to be a problem in most installations during normal Indian climatic conditions, but it may occur during the periods of very cold, dry weather, specially in those departments which are heated and mechanically ventilated without humidification. It is also likely to occur in air-conditioned areas if the humidification plant is not functioning properly.

A-7.2.3 Textiles should be allowed a period of not less than four hours for airing after laundering before they are sterilized.

A.8. MEASUREMENT *OF* DRYNESS FRACTION

A-8.1 Where problems with superheating and/or wet loads cannot be readily overcome, it is desirable to measure dryness fraction in order to quantify the problem. The most successful method involves sampling the steam throughout the air removal stage. The sample should be collected by inserting a capillary probe (pitot) into the centre of the steam pipe (see Fig. 1). The diameter of the probe should be in accordance with Table 1.

TABLE 1 CAPILLARY PITOT TUBE DIAMETERS

STEAM PRESSURE BAR	DIAMETER mm BORE
(1)	(2)
7	0'71
4	0.96

NOTE 1 — By taking a 'core' sample from the steam supply line, a close approximation to chamber conditions is obtained, with the minimum of entrained condensate.

NOTE 2 — A single pan laboratory balance of 1'5 kg capacity has been found most satisfactory for the accurate weighing, that is, necessary with this technique.

A-8.1.1 *Method* — Steam is injected during the air removal stage into a calorimeter (1-litre thermos flask) which contains a known mass of water at a known temperature. At approximately 80-85°C, the steam is cut off by disconnecting the rubber tube so that the steam has been sampled during the most active period of steam injection to the sterilizer, that is, from the commencement of air removal to just after the start of sterilizing 'hold'.

Since the increase in mass and temperature is known, the dryness fraction can be determined from heat balance. A typical equation is shown below:

Let T_1 = temperature of water at the beginning of the test (°C);

T_2 = temperature at the end of the test (°C);

T_3 = temperature of steam (°C);

L = latent heat of steam at T_3 (from steam tables) (kJ/kg);

D = dryness fraction of steam;

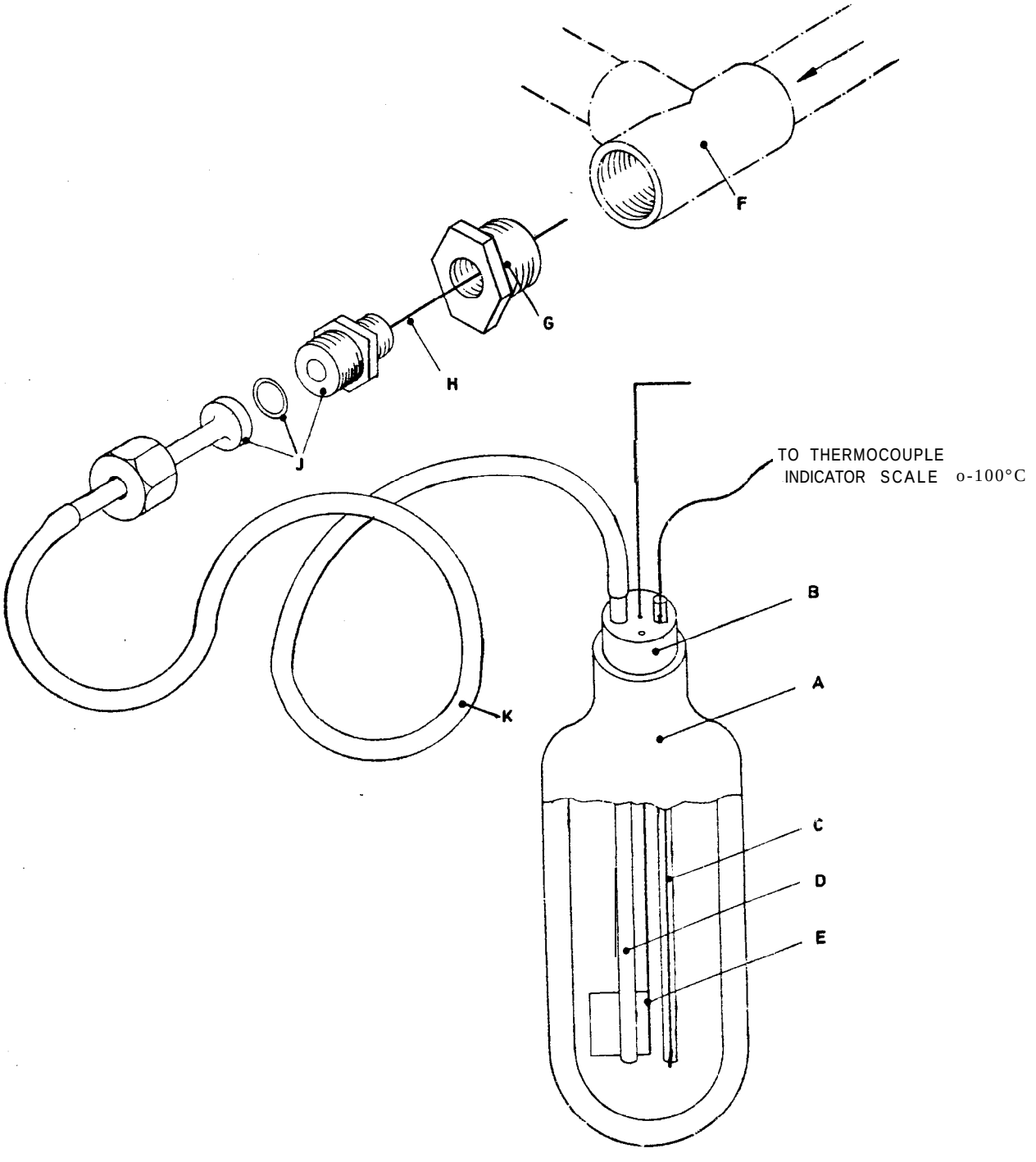
W_s = weight of thermos at the beginning of the test (kg);

W_f = weight of thermos at the end of the test (kg);

W_c = weight of condensate collected (kg);

W_w = weight of initial water charge (kg);

W_t = total weight of thermos plus bung, tubing, etc, excluding water;



A — 1-litre flask

B — Rubber bung (drilled to accommodate 2 glass tubes — Push fit stirrer and 3 mm dia vent-hole)

C — Thermocouple tube 7 mm OD/5 mm ID, 300 mm long glass. Thermocouple hot junction to be positioned at the lower end of the tube.

D — Stream sponge tube 7 mm OD/5 mm ID, 300 mm long glass.

E — Stirrer 2·0 mm OD brazing wire with 25 mm square x 0·90 mm dia paddle brazed to end.

F — 'T' in steam line to sterilizer.

G — Reducing bush.

H — Capillary probe brazed into union.

J — *'0'* ring union fitting.

K — Rubber tube 8 mm OD, 300 mm long.

FIG. 1 APPARATUS FOR DETERMINATION OF DRYNESS FRACTION

W_1 = weight of glass thermos (consider only the glass, excluding one weight of canister) (kg);

W_2 = weight of glass tubing (kg);

W_3 = weight of rubber bung and tubing (kg);

W_4 = weight of brass stirrer (kg);

W_5 = weight of entire flask (canister but not lid) (kg);

S_1 = specific heat of glass [650 (nom) J/kg °K];

S_2 = specific heat of rubber (2 009 J/kg °K);

S_3 = specific heat of brass (370 J/kg °K); and

S_4 = specific heat of water (4 180 J/kg °K).

NOTE — It is assumed that the effective weight of thermos flask! rubber bung and tube are 75 and 25 percent, respectively.

Heat gained by thermos

$$= 0{\cdot}75\, W_1 (T_2 - T_1) \times S_1$$

Heat gained by glass tubing

$$= W_2 (T_2 - T_1) \times S_1$$

Heat gained by the rubber bung and tubing

$$= 0.25\, W_3 (T_2 - T_1) \times S_2$$

Heat gained bythe stirrer

$$= W_4 (T_2 - T_1) \times S_3$$

Heat gained by water in the flask

$$= W_w (T_2 - T_1) \times S_4$$

Therefore, total heat gained

$$= (T_2 - T_1) (0{\cdot}75\, S_1 W_1 + W_2 S_1 + 0{\cdot}25\, S_2 W_3 + S_3 W_4 + S_4 W_w)$$

Total heat lost

$$= W_c \times D \times L + W_c (T_3 - T_2) S_4$$

$$W_t = W_5 + W_2 + W_3 + W_4$$

$$W_w = W_s - W_t$$

$$W_c = W_f - W_s$$

Rewriting and solving for dryness fraction:

$$D = \frac{(T_2 - T_1)\, 0{\cdot}75\, S_1 W_1 + S_1 W_2 + 0{\cdot}25\, S_2 W_3 + S_3 W_4 + S_4 (W_s - W_t) - (W_f - W_s) (T_3 - T_2) S_4}{(W_f - W_s)\, L}$$

Using the apparatus shown in Fig. 1 and the sizes given for various components (see also Table 1) and taking into account the order of magnitude of the various elements, the equation may be reduced further with a loss of accuracy which should not exceed 1 to 2 percent.

Let T_1 = initial temperature of water in the flask (°C);

T_2 = final temperature of water and condensate in the flask (°C);

T_3 = average steam temperature during sampling period (°C);

L = latent heat of steam at T_3 (from steam tables) (kJ/kg);

W_s = weight cf flask, stirrer, etc, and water charge (kg);

W_f = weight of flask, stirrer, etc, water and condensate (kg);

$$D = \frac{(T_2 - T_1)(4{\cdot}18\, W_s - 2{\cdot}544)}{L (W_f - W_s)} - \frac{(T_3 - T_2)\ 4.18}{L}$$

APPENDIX B

(Clauses 2.3, 6 1.2, 6.2.16, 7.11.2, 8.1.1 and 11.3.1)

INSTRUMENTS TO BE MOUNTED ON STERILIZERS AND FOR TESTING AND COMMISSIONING STERILIZERS AND TO BE VISIBLE TO THE OPERATOR

B-1. GENERAL

B-l.1 Where more than one gauge or instrument is fitted in the same area, every effort should be given to obtain a uniform appearance, for example, circular pressure and temperature gauges.

B-1.2 The errors produced in temperature and pressure measurement using either indicators or recorders arise from a number of factors. Some of these are inherent in the design, age and conditions of the measuring equipment. Others are brought about by the conditions on site, the day-to-day variations in atmospheric conditions and the skill and experience of the operator. Still others arise from permissible variations in thermocouple alloys, and even the positioning of the thermocouples within the load can produce misleading readings. Loose terminals and imperfect plug and socket connections will also cause errors.

B-l.3 Every effort should be made to eliminate or minimize these errors by attention to detail in design, effective maintenance and skill in the application and use of the instruments.

B-1.4 The levels of accuracy stated in this appendix assume that the instruments and controllers are designed, chosen and located in a manner which will ensure a long trouble-free life under varying conditions of temperature and humidity to which they will be subjected. The normal ambient temperature in the plant room with the plant idle, may be between 10 and 30°C, and up to 40°C with the plant running.

B-1.5 All instruments should comply with the relevant Indian Standards. The sterilizer manufacturers must carry out adjustments to the instruments on site, as necessary, so that the additional requirements of this appendix can be met with the 'plant running' conditions normally prevailing on site. Accurate test instruments and test procedures for site calibration are described in B-7.1.1 to B-10.7.

B-2. INDICATING THERMOMETERS

B-2.1 Indicating thermometers must be either Types 1, 2 or 3 as follows:

a) *Type 1* — Dial type expansion thermometers, liquid or gas filled or in the case of bench top machines and hot air sterilizers, vapour pressure instruments.

The scales of the last-named are non-linear and for this reason, vapour pressure instruments are not preferred. The thermometers should be generally be in accordance with Table 2.

TABLE 2 SCALES FOR INDICATING THERMOMETERS

Standard Requirements		Exceptions for Bench Top Electrically Heated Unwrapped Instruments and Utensil Sterilizers	
		Single Function Instruments	Dual Function* Instruments
(1)	(2)	(3)	(4)
Nominal size (dia)	100 mm	50 mm	50 mm
Minimum scale length,	160 mm	90 mm	50 mm
Scale range (Max)	150°C†	150°C	150°C
Graduations over effective range	2°C	5°C	5°C

*These indicate temperature and pressure but must have separate sensors for temperature and pressure.
†200°C for hot air sterilizers.

b) Type 2 — Indirect electrical indicating instruments are calibrated either for resistance elements or for a particular type of thermocouple.

It should be noted that thermocouple instruments indicate correctly only when used with the class of thermocouple for which they are calibrated (see B-7.6.1 to B-7.6.7). Instruments for mounting on machines must be as in Table 3.

NOTE — Where a scale is used, it should have a scale length of not less than 120 mm; however, the newer style of 'ribbon' indicator with a scale length of 100 mm is acceptable because of better resolution with this type of scale. The scale should be calibrated 0-150°C (0-200°C for hot air sterilizers) with graduations at 2°C intervals (if digital instruments are used, the maximum increment to be displayed should be 0·5°C). Semi-conductor resistance elements (including thermistors) may be used where the normal maximum temperature does not exceed 160°C. The instruments must have broken sensor protection giving full scale deflection. Where the instrument is to be used to provide a limited control function, the broken sensor protection must fail safe; the sterilizer manufacturer should state whether up-scale or down-scale drive is required on failure.

TABLE 3 SELECTION OF INSTRUMENTS

(*Clauses* B-2.1 and B-4.4)

Calibrated for use with	Relevant Indian Standard
(1)	(2)
Resistance elements	IS : 2848-1986*
Thermocouples	IS : 7358-1984†
	IS : 2054-1962‡
	IS : 10625-1983§

*Specification for industrial platinum resistance thermometer sensors (*first revision*).
†Specification for thermocouples (first revision).
‡Reference tables for nickel/aluminium nickel/chromium thermocouple.
§Reference tables for nickel/chromium-copper/nickel (chrome1 constantan) thermocouples.

c) Type 3 — Dial type expansion thermometers of the bi-metallic type. These may be suitable for use in certain situations where direct connection between sensing and indicating elements is possible (for example, without the use of capillary tubes). This type is often sensitive to vibration, such as by door slamming, and must, therefore, be of a design which allows for such treatment. They will normally be suitable for use only on hot air sterilizers. In this situation alone, they may also be used to operate in conjunction with timers and door interlocks but not to control the chamber temperature. They must be of the type with the element sealed in a stainless steel stem.

B-2.2 Table 4 indicates ideal scale ranges for various types of sterilizers, the actual scale varying from manufacturer to manufacturer.

B-Z.3 The indicating instrument may sense the temperature at a point indicated in Table 5.

TABLE 4 TYPICAL ACCEPTABLE RANGES FOR THERMOMETRIC SCALES

(Clause B-2.2)

TYPE OF STERILIZER	SCALE °C
(1)	(2)
Fluids	40-160
Porous loads	60-180
Unwrapped instruments and utensils	60-180
Hot air	50-200

NOTE — Separate systems must be used for:

a) Indicating thermometer (for temperature indicator/controller where permitted in R-Z.5),

b) The recorder, and

c) Temperature interlock for fluid sterilizers. The interlock to prevent opening of the door with load temperature in excess of 80°C should be controlled only by means of a load simulator and not directly from a load bottle.

TABLE 5 SENSOR LOCATIONS FOR INDICATING THERMOMETERS AND TEMPERATURE RECORDERS AND CONTROLLERS

(Clause B-2.3)

TYPE OF STERILIZER	CHAMBER DRAIN	COLDEST PART OF CHAMBER STEAM SPACE (OR CHAMBER FREE SPACE)	AIR VENT
(1)	(2)	(3)	(4)
Porous load	Yes	No	NA
Fluids with chamber drain	Yes	No	NA
Fluids without chamber drain	NA	Yes	Yes
Unwrapped instrumeots and utensils, with chamber drain	Yes	No	NA
Unwrapped iostrumeots and utensils, without chamber drain	NA	Yes	Yes
Hot air	NA	Yes*	Yes

*This **may be either in the air circulation system or in** a position agreed with the manufacturer; this may not however, be the coldest part of the chamber [the coldest part of the chamber or load may be up to 5°C lower — *see* N-2.7 (d)].

B-2.4 The maximum error should not exceed 1°C at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, for example, **136°C for a range** 134^{+4}_{-0} **°C. The** permissible error stated here is for an instrument mounted in a vertical position **in** an ambient temperature **of 20 ± 5°C with the difference in level between the sensor and the** instrument **as it occurs on the sterilizer. This degree of accuracy will not be achieved if the ambient temperature is outside the limits stated. The instrument should incorporate a means of adjustment for setting on site so that the accuracy required at the mean sterilizing temperature is achieved (see B-1.5).**

B-2.5 The indicating thermometer may only be used for control purposes if the control function does not affect the indication of the temperature, This limitation need not apply in the case of a hot air sterilizer provided that the effect of any control function is restricted to a depression in indication of a rising true temperature not exceeding 1·5°C or 1·5 percent of the scale span, whichever is lesser,

B-3. PRESSURE GAUGES

B-3.1 Pressure gauges should preferably be of the Bourdon tube type. It is the normal practice of many sterilizer manufacturers to fit pressure gauges without syphons. A pressure gauge should not be directly exposed either to steam or to working fluid at a temperature in excess of 100°C. For these reasons, the accuracy stated for the scale range cannot be guaranteed though sterilizer manufacturers can ensure that the stated accuracy can be achieved by calibration at the operating temperature.

- There is little practical evidence to support the omission of syphons on modern sterilizers and it may now be preferable to fit them, in order to maintain the Indian Standard accuracy of the instruments. The instrument should incorporate a means of adjustment for setting on site, so arranged that authorized persons may be able to make the adjustment without having to dismantle the instrument.

B-3.2 The size and length of scale should be as in Table 6.

TABLE 6 SIZE AND SCALES (LENGTH) FOR PRESSURE GAUGES

STANDARD REQUIREMENTS		EXCEPTIONS FOR BENCH TOP ELECTRICALLY HEATED UNWRAPPED INSTRUMENTS AND UTENSIL STERILIZERS	
		Single Function Instrumeots	Dual Function* Instruments
(1)	(2)	(3)	(4)
Nominal (dia)	**size 100 mm**	50 mm	50 mm
Minimum scale **length**	160 mm	90 mm	50 mm

***These** indicate both pressure and temperature but **must have separate sensors for pressure** and **temperature.**

B-3.3 The scale should be as in Table 7.

TABLE 7 SCALES FOR DIAL TYPE PRESSURE GAUGES

(*Clauses* B-3.3 *and* B-4.9)

DUTY	SCALE (As DEFINED IN IS : 3624-1987*)	GRADUATION INTERVALS (mbar)	
		Nominal 100 mm Dials	Nominal 50 mm Dials
(1)	(2)	(3)	(4)
Leak testing	0-150 mbar (absolute), *Max*	2	†
Fluids	0 to 2·5 bar‡	100	†
Porous loads chamber	— 1 to +5 bar	200	†
Unwrapped instruments and utensils (chamber)	-1 to +5 bar, or 0 to 4 bar	200 200	† †
Porous loads and unwrapped instruments and utensils (jackets)	0 to 4bar	200	†
Electrically heated bench top unwrapped instruments and utensils sterilizers — single function gauges and dual function gauges§	0 to 4 bar	200	200

*Specification for pressure and vacuum gauges (*second* revision).

†This size of instrument is unsuitable for this duty.

‡May be 0 to 4 bar non-rigid containers.

§Dual function gauges are combined temperature and pressure instruments.

B-3.4 The error in pressure indication should not exceed ± 1 percent of the scale range at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, for example, 136°C for 134^{+4}_{-0} °C range.

NOTE — It is essential that where two pressure gauges are connected to the same source of pressure (such as inter-connected chamber and jacket), they should be set on site to indicate identical pressure within the above limits of accuracy.

B-3.5 The leak rate testing gauge should respond to any change of pressure exceeding 1 mbar.

B-3.6 The gauge should be suitable for operation either when exposed directly to steam at 2·8 bar or when connected to the chamber via an automatic isolating valve. This valve must prevent exposure of the gauge to steam and to pressures in excess of atmospheric pressure.

NOTE -The continuing availability of barometrically compensated absolute pressure gauges within reasonable costs is doubtful. Instrumentation for leak testing is under review. A vacuum gauge with sensitivity in accordance with B-3.5 should be adequate. The variation in vacuum achieved by the machine under various conditions of atmospheric pressure should be indicated by a coloured band or similar means. Calibration may be over the entire range of scale or over a 15 mbar range inscribed on a rotating bevel ring.

B-4. TEMPERATURE RECORDERS AND COMBINED TEMPERATURE/ PRESSURE RECORDERS

B-4.1 A temperature recorder should be fitted to monitor the performance of each sterilizer for porous loads, each sterilizer for fluids in sealed containers and each hot air sterilizer. It is not mandatory to fit any recorder to a sterilizer for unwrapped instruments and utensils but there are many situations in which its use can be justified, particularly in some operating theatres.

B-4.2 Recorders should not be used to control either temperature or pressure in the chamber or any safety interlocks.

B-4.3 All recorders should incorporate a means of adjustment for setting on site.

B-4.4 The thermometric measuring system should sense the temperature at a point as indicated by one of the following means:

a) **Indirect acting electrical, either with resistance elements or with thermocouples as in Table** 3. Semi-conductor elements (including thermistors) may be used where the normal maximum temperature does not exceed 160°C; they are not, therefore, normally suitable for use in hot air sterilizers.

b) Liquid expansion system (vapour pressure instruments are unsuitable for this application).

B-4.5 The recorded temperature should be within ± 1°C at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, for example, 136 °C for a 134^{+4}_{-0} °C range. The temperature chart should be scaled with a maximum range of 150 °C (200°C for hot air sterilizers) and a minimum range of 100°C, with lines at intervals representing a division not exceeding 2°C (5°C for hot air sterilizers).

B-4.6 Electrical instruments should comply generally with IS :302-1979*, with broken sensor protection. Where the instrument is to be used to provide a control function (see B-4.2), the broken sensor protection should fail safe; the sterilizer manufacturer should, therefore, state whether up-scale or down-scale drive on failure is required.

B-4.7 **The** pressure measuring system on a combined temperature/pressure recorder will normally incorporate a Bourdon tube. The problem of connecting pressure recorders is the same as that arising with pressure gauges and the solution is similar (see B-3.1).

*General and safety requirements for household and similar electrical appliances (*fifth revision*).

B-4.8 Other pressure recording systems may be used provided they are suitable for the application and are no less accurate than the approved Bourdon system.

B-4.9 The error in recorded pressure should not exceed ± 1 percent of the scale range at sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, for example, 136% for 134 $^{+4}_{-0}$°C range. The pressure measuring system should be suitable for the ranges specified for pressure gauges in Table 7.

B-4.10 On combined instruments, the scale lines on the chart should be common for the temperature and pressure record, the temperature record taking precedence for the major scale lines.

B-4.11 The recording charts may be either circular or strip charts (preferably the latter) and should provide a permanent and immediately visible record. If strip recorders are used, they should preferably incorporate either a tear-off facility or be suitable for Z-fold charts. It will be necessary to remove the chart on completion of the process so that roll on or pull through is required. Circular charts should preferably be not less than 240 mm in diameter, with a radial scale length not less than 100 mm. Strip charts should not be less than 90 mm wide. Recorders printing on cards may offer an alternative, but in this case it is advisable to provide an interlock to prevent commencement of the cycle until a card is inserted (The record is, unfortunately, not normally immediately visible with card instruments).

B-4.12 Selection of an appropriate chart speed will be dependent upon the type of recorder chosen and the process being monitored. Separate charts for each cycle are preferred when medicinal products are sterilized [see D-8.8.4 (k)]. Chart speeds should be as given in Table 8.

TABLE 8 CHART SPEED FOR TEMPERATURE RECORDERS MOUNTED ON STERILIZERS

Type of Recorder Chart Speed	Circular hours/ revolution		Strip mm/min	
Process	*Max*	*Min*	*Max*	Min
(1)	(2)	(3)	(4)	(5)
Porous load	3	2	20	5
Fluids, rapid cooling	3	2	8	2
Fluids, natural cooling	3	2	2	1
Hot air	12	6	2	1

B-4.13 Pressure recording systems of the Bourdon tube type can normally be fitted to instruments using either electronic or expansion thermometric systems but, as a rule, they are used only with circular chart recorders.

B-4.14 Pressure transducer systems are compatible with strip chart recorders but are not generally available within the price range of a comparable mechanical system.

B-5. CYCLE STAGE INDICATOR

B-5.1 Means must be provided to indicate each stage in progress at any time, such as, air removal, sterilizing, cycle completed,

B-6. CYCLE COUNTER

B-6.1 A four-digit cycle counter must be provided to indicate the cumulative total of completed cycles regardless of whether they are sterile or non-sterile. The counter should be tamper-proof or sealed, and be non-resettable.

B-7. INSTRUMENTS FOR TEST PURPOSES

B-7.1 Temperature Recorders — General

B-7.1.1 The requirement embraces instruments used for:

a) commissioning sterilizers,

b) re-commissioning sterilizers which have undergone major overhaul, and

c) periodic testing of sterilizers in service.

B-7.1.2 The instruments should be of the indirect acting electrical type, for use with thermocouples. Instruments calibrated with iron/copper-nickel thermocouples are not suitable for use with sterilizers because of corrosion problems (The use of resistance elements is impracticable for testing some sterilizers). Details of the Indian Standard requirements are given in Table 9. They relate to the instruments only, that is, they do not allow for errors arising from the thermocouples. Facts relating to accuracy of measurement achieved in practice are given in subsequent paragraphs (see also B-7.1.6).

B-7.1.3 The two instruments will have the intrinsic accuracy stated in Table 9 only under the reference conditions stated in Table 10.

B-7.1.4 The accuracy of the two instruments is permitted to vary from the values in column 5 of Table 9 for wider ranges in the reference conditions. The additional error permitted by the extreme limits is shown in Table 11 for the more usual influence quantities.

Typical values are quoted in Table 11 for the permissible limit of error for automatic cold junction compensation.

B-7.1.5 The permissible errors may be aggregated statistically but the instrument should be fitted with span and zero adjustment controls for the purpose of site calibration (see Note). The errors shown in Table 11 are the maximum allowable; most instruments are capable of achieving greater accuracy (see B-7.1.6).

Note — Defined as the range within which the measured quantity may be varied without initiating a movement of the indicating or recording device.

TABLE 9 SPECIFICATION FOR TEMPERATURE RECORDERS REQUIRED FOR TEST PPUROSES

(Clauses B-7.1.2, B-7.1.3 *and* B-7.1.4)

DUTY	USUAL CHART WIDTH, mm	MINIMUM NUMBER OF CHANNELS	MINIMUM CHART SPEED, mm/min	INTRINSIC ERROR, % OF SCALE SPAN	DEAD BAND, % OF SCALE SPAN
(1)	(2)	(3)	(4)	(5)	(6)
1. Commissioning, re-commissioning and yearly testing of fluids and hot air sterilizers	250	12	5	0·5	0'25
2. Commissioning, re-commissioning and yearly testing of other sterilizers	250	3	20	0·5	0·25
3. Other periodic testing of fluids and hot air sterilizers	100	3	5	1'0	0'5
4. Other periodic testing of other sterilizers	100	3	20	1'0	0·5

TABLE 10 SOME BASIC REFERENCE CONDITIONS FOR INSTRUMENTS

(Clause B-7.1.3)

INFLUENCE QUANTITY	REFERENCE CONDITION (UNLESS OTHERWISE STATED)	TOLERANCE FOR A SINGLE REFERENCE VALUE
(1)	(2)	(3)
Ambient temperature	20°C	±1°C
Relative humidity	50%	40 to 60%
Supply voltage	Rated	±1%

B-7.1.6 The instrument should be calibrated at the test site before a test is commenced. When this is done, the combined error arising from instrument and thermocouple is unlikely to exceed 0·75°C (see Note) for the sterilizer engineer's instrument.

NOTE — This error may be increased as a result of cold junction compensation error. The importance of stable temperatures and avoidance of draught is emphasized.

B-7.1.7 Ideally, these instruments should have interchangeable scales and circuitry, calibrated 0-150°C and 50-200°C, with the range change made, preferably, by an integral switch. If, for any reason, it is proposed to use a single scale instrument, this should be calibrated 0-200°C.

B-7.1.8 The instrument should provide, simultaneously, a scale indication and a permanent and immediately visible record with the cover closed.

B-7.1.9 The record should be colour coded or colour coded and numbered. Six colours are usually adequate provided they are printed in two different symbols.

B-7.1.10 Each instrument should be used only with the class of thermocouples for which it is calibrated.

B-7.1.11 The commissioning, re-commissioning and annual test requirement can best be met by a 12-channel recorder. It may be used for all types of sterilizers. For all periodic testing, except the annual test, a 3-channel instrument may be used.

TABLE 11 ADDITIONAL ERROR PERMITTED FOR EXTREME LIMITS

(Clauses B-7.1.4 *and* B-7.1.5)

INFLUENCE QUANTITY	LIMIT OF PERMISSIBLE RANGE	ADDITIONAL PERMISSIBLE ERROR AT LIMIT OF PERMISSIBLE RANGE OF A SINGLE INFLUENCE QUANTITY	
		Commissioning Instruments (% of scale span)	Periodic Testing Instruments (% of scale span)
(1)	(2)	(3)	(4)
Ambient temperature	±10°C	0'1	0'2
Rated voltage of power supply	+5 to −15%	0·125	0·25
Automatic cold junction compensation	—	0'04°C per deg change	0'04°C per deg change

B-7.1.12 The 12-channel instruments are all very expensive, very large and very heavy.

B-7.1 .13 All these instruments need considerable care in handling and transport if they are to maintain their accuracy; they deteriorate if not regularly used and for this reason, should not normally be held at hospital or district level.

B-7.2 **Particular Details of 12-Channel Temperature Recorder**

B-7.2.1 The instrument should have a maximum dotting interval of 3 seconds per point, that is, a rated duration of cycle not exceeding 36 seconds when recording 12-channels.

B-7.2.2 When a test requires fewer channels than those available in the instrument, it is desirable to ensure that the specified dotting interval between monitored positions is not exceeded, that is, when three positions are to be monitored, the effective scan time does not exceed 9 seconds, or if two positions are to be monitored, the effective scan time does not exceed 6 seconds. It is possible to accomplish this by various means, such as:

a) Using one thermocouple for each monitored position and inter-connecting channels in parallel groups by identical thermocouple wire, and

b) Changing printed circuit boards in the instrument (the instrument should be recalibrated whenever a printed circuit board is changed).

B-7.2.3 In all cases, it is helpful if the printing head can be changed so that each record is in one colour only (although it may be made up of a variety of symbols).

B-7.3 **Particular Details of 3-Channel Temperature Recorder**

B-7.3.1 The instrument should have a maximum dotting interval of 10 seconds per point, that is the total rated duration of cycle not exceeding 30 seconds when recording 3-channels. If the instrument is required to monitor one or two positions, the rated duration of the cycle should be reduced to 10 or 20 seconds, preferably by cross-connecting the channels in parallel or alternatively, by using more than one thermocouple to monitor one position. In either case, it is helpful if the printing head can be changed so that each record is in one colour only.

B-7.3.2 When monitoring two points only, for example, the drain and the centre of the pack in porous load tests, it is desirable that the pack and not the drain is recorded twice in a J-channel scan.

B-7.3.3 There is some merit in using a continuous trace instrument for these tests.

B-7.4 Test Thermometers

B-7.4.1 Thermometers should be laboratory thermometers and of the partial immersion type, The most appropriate instruments will be of the following ranges:

a) 2 to 52°C,

b) 48 to 102°C,

c) 98 to 152°C, and

d) 123 to 177°C.

They should be specified as having a stem diameter of not less than 7·0 mm. They are designed for 125 mm immersion and are 405 mm long.

WARNING — *NO* MERCURY-IN-GLASS THERMOMETER SHOULD BE USED INSIDE A STEAM CHAMBER.

B-7.5 **Test Pressure Gauges**

B-7.5.1 These may be Bourdon test gauges. If they are not designed for direct connection to steam at 2·8 bar, they should be connected via a syphon. They should be calibrated 0 to 150 mbar absolute and −1 bar to 0 for vacuum gauges and 0 to 2·5 bar for pressure gauges. They should be scaled as shown in Table 12.

TABLE 12 SCALES FOR TEST PRESSURE GAUGES (DIAL TYPE)

SCALE	GRADUATIONS
(1)	(2)
0 to 150 mbar absolute	0·5 mbar
−1 to 0 bar	5 mbar
0 to 2·5 bar	20 mbar
−1 to 4 bar	25 mbar

B-7.5.2 The minimum scale length should be 260 mm and the nominal diameter shall be not less than 150 mm. They should be tested by a recognized testing laboratory and the error should not exceed 0·25 percent of the maximum scale range. Other test gauges may be used provided they are suitable for the purpose and provided they are no less accurate than what is prescribed for Bourdon test gauges.

B-7.6 **Construction and Use of Thermocouples**

B-7.6.1 Thermocouples should conform to IS : 7358-1984.

*Specification for thermocouples (*first* revision).

B-7.6.2 It is essential to use thermocouple wire of known output which has previously been checked off site. This problem of purchasing presents difficulties and draws attention to the inherent variations in performance of every reel of thermocouple wire and a part thereof, as well as the errors arising from imperfections in the actual jointing techniques.

B-7.6.3 Thermocouple wire is available, marked to show the limits of variation of the reel from the figures given in the relevant Indian Standard. The variation will have been established by the manufacturer by testing samples from both ends of the full reel, and for 'selected' wire this is typically of the order of 0·015 millivolts (for copper/constantan) which is equivalent to 0·4°C at 20°C and 0·3°C at 134°C. 'Selected' rather than 'standard wire should be used for this reason.

B-7.6.4 The wire should be single strand, not exceeding 0·7 mm in diameter over the covering, and single core or twin core. Tracking of steam along the wire to the centre of the Bowie/Dick tape test pack may be a problem with the bulkier twin core wire, thus defeating the object of the test. If it is used, it will be necessary to take extra care to minimize disturbance of the towels. Steam or fluid may be forced through the wire sheath, particularly fluid when thermocouples are used in bottles. The sheath should be stripped back for a few inches before connecting the wires to the recorder so that any droplets forming where the sheath has been terminated, fall clear of the instrument. Twin core wire is usually preferred because it is easier to handle and is more durable than single core wire.

B-7.6.5 Thermocouple should preferably be argon-arc welded or microwelded; alternatively, they may be suitably cleaned and twisted, or crimped together with purpose-made ferrules, to form the hot junction. Brazing, silver brazing and welding with filler rods may be no more reliable in respect of accuracy than twisting or crimping. If welding is not employed (and it rarely is in the field), it is a good practice to use new thermocouples each time a sterilizer is monitored. If reasonable care is taken, specially with outer sheathed wire, it is often possible to re-use the wire several times, provided any twisted or crimped joints are re-made. Thermocouples should not be fitted with a heat sink, neither should they be 'slugged'.

B-7.6.6 Three typical methods of introducing thermocouples into sterilizer chambers are illustrated in Fig. 2, 3 and 4. Some manufacturers adopt other solutions, some of which are to be discouraged because they prevent the removal of individual thermocouples. In those machines having no thermocouple entry socket, entry may be made via a tee which can usually be inserted into a service entry pipe (for example, steam supply pipe) to the chamber. The thermocouples should not be introduced through the door seal except as the last resort.

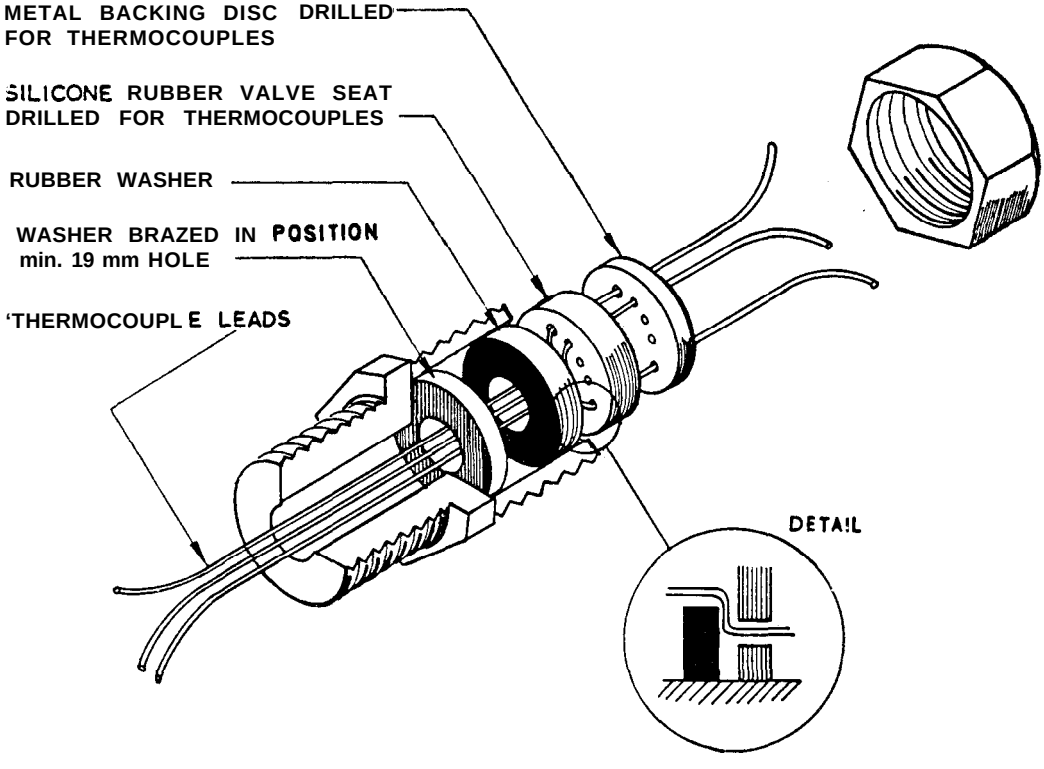


FIG. 2 METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER SUITABLE FOR UP TO 12 TWIN CORE THERMOCOUPLES

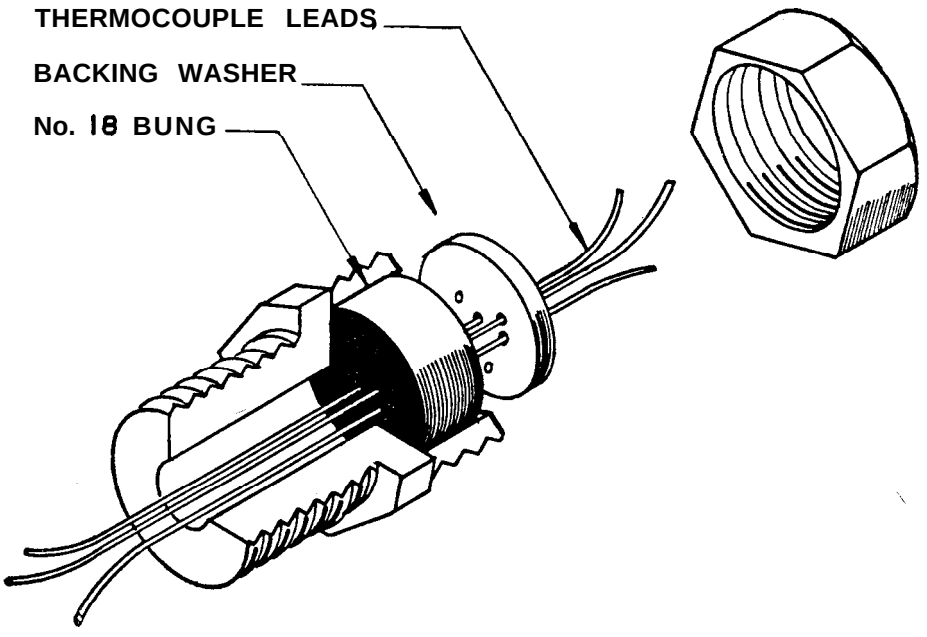


FIG. 3 METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER SUITABLE FOR UP TO 6 TWIN CORE THERMOCOUPLES

B-7.6.7 Entry of thermocouples through bottle caps may be made by means of a trocar and cannula; any other suitable method may be used. It is essential that the sealing of the bottle remains effective with the thermocouples in position.

B-8. CALIBRATION OF TESTING INSTRUMENTS AT STERILIZER TEST SITE — GENERAL CONSIDERATIONS

B-8.1 A functional test of the temperature recorder should be carried out on site as recommended by the makers after any range change, and after span and zero adjustment (see B-7.1.5) by one of the following methods:

a) Thermocouple immersed in oil bath,

b) Potentiometer and standard cell, and

c) Millivolt source.

NOTE — The technique employing thermocouples immersed in boiling water is only of use for rough checking purposes: it may be affected by the *p*H of water. If the method has to be adopted, the calibration should be checked against a standard thermometer, immersed with the thermocouples, using distilled or purified water. The normal extremes of atmospheric pressure result in a change in the boiling point of approximately ±2°C. Also, any increase of 150 m above mean sea level will reduce the boiling point by approximately 0'5°C.

B-8.2 All electronic test instruments should be allowed a period of at least 2 hours within the test site environment to enable the instruments to stabilize with the mains switched on.

B-8.3 All thermocouples used should be checked again after completion of the tests on the sterilizer before they are disconnected from the instrument (see B-13.1).

B-9. CALIBRATION OF TEST INSTRUMENTS BY OIL BATH

B-9.1 There are two main versions of the oil bath; the first is one in which the oil is in a bath, usually, with a magnetic stirrer or fluid circulator, and the second, which is to be preferred, where the oil is held in pockets in a large, electrically heated aluminium block.

The oil is normally a silicon fluid, for example, that used for the basic performance test for hot air sterilizers (see Appendix N).

NOTE — If the thermocouples are not welded, there may be difficulty in achieving the prospective degree of accuracy because of the insulating property of the oil. For this reason, additional care is required if mechanical jointing is proposed, and this is the reason why microwelding or argon-arc welding is the preferred method (*see* B-7.6.5).

B-9.2 The recorder is first adjusted in accordance with the maker's instructions. This usually involves zero and span adjustments. Any range change should be effected before these adjustments are made.

B-9.3 The thermocouples are immersed in heated oil bath together with a standard thermometer. Support clamps are available and may be used with advantage to hold the thermocouples and thermometer closely together. The stirrer should be used to maintain a uniform oil temperature, and readings should be taken with the temperature on a rising cycle and at the sterilizing temperature. It may be necessary to add small quantities of cold oil to ensure that the readings are taken with rising rather than falling oil temperature.

NOTE — In practice, this is difficult to effect and it may be more convenient at this stage to check one of the thermocouples only (*see* B-13.1).

B-9.4 The electrically heated block form of oil bath has the advantage of greater portability since it is necessary only to use sufficient oil to ensure intimate contact between thermocouples, the standard thermometer and the test block.

B-9.5 The oil-bath method of calibration also suffers from the lack of uniformity in the thermocouple wire referred to in B-7.6.2. The inherent inaccuracy of the potentiometer is eliminated but both the hysteresis of the mercury and glass thermometer, and the temperature gradient within the oil, can give rise to errors unless great care and skill are applied. If these errors can be eliminated or discounted, the limits of accuracy are those imposed only by the dead band of the recorder.

B-10. CALIBRATION OF TEST INSTRUMENT BY POTENTIOMETER AND STANDARD CELL

B-10.1 The potentiometer used for this purpose should have an error not exceeding 0·1 percent of the scale range, or 5 microvolts, whichever is greater.

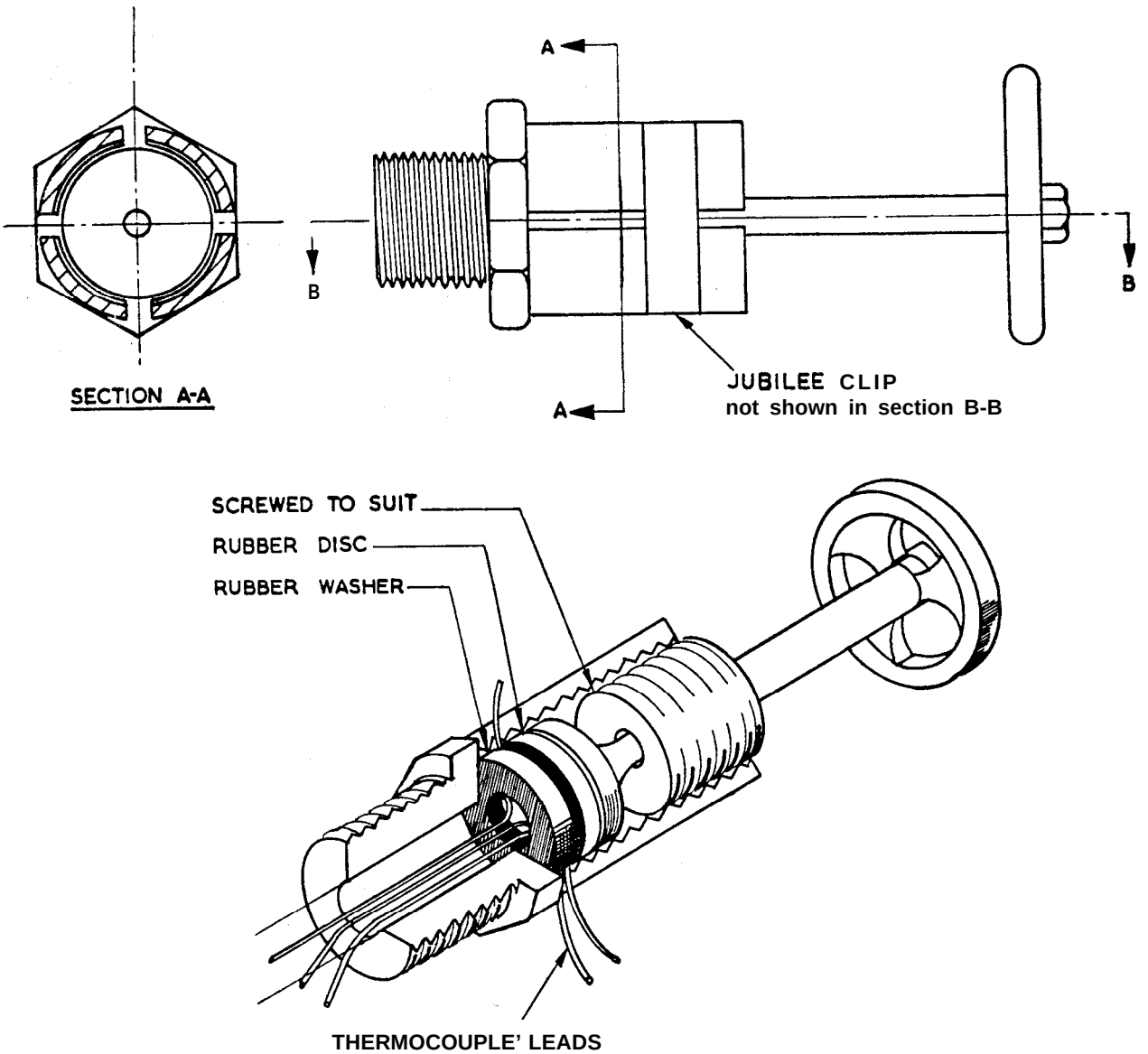


FIG. 4 METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER SUITABLE FOR UP TO 12 THERMOCOUPLES OF EITHER TWIN OR SINGLE CORE WIRE

B-10.2 It must first be standardized in accordance with the maker's recommendations. This usually involves adjustment of the cold junction temperature setting in accordance with the reading of a thermometer on the instrument itself. The potentiometer is then set to give a millivolt output corresponding to the sterilizing temperature of the test.

B-10.3 The recorder is then adjusted in accordance with the maker's recommendations (*see* B-8.1). The millivolt output from the potentiometer is connected to the input terminals of one channel on the recorder and the instrument is adjusted in accordance with the maker's instructions so that it indicates 134°C.

B-10.4 In order to minimize the effect of the inherent error of the thermocouples, it is desirable to make up (off the sterilizer site) a set (of 12 or 3 plus two matching spares) from the same reel of wire and chosen by test against a potentiometer so that they have, as near as possible, an identical performance.

B-10.5 The average emf output of the set thermocouples should be measured by the potentiometer, with one of them attached to a standard thermometer in an oil bath at the sterilizing temperature (see **B-9.1** to B-9.5). For example, with the oil bath at 134°C, the difference between the thermocouple emf and the Indian Standard thermocouple emf is found to be 0·012 mV (5·131 mV measured, 5·119 mV standard). This variation is actually equivalent to +0·25°C. The recorder should then be re-set, on the sterilizer site, to indicate 134°C with an input of 5·131 mV from the potentiometer (that is, to indicate 133·75°C at 5·119 mV).

B-10.6 It is recognized that in many instances, it will not be practicable to prepare thermocouples off the sterilizing site and, in such cases, the calibration of the recorder should be done by one of the other methods referred to in B-8.1.

B-10.7 The limits of accuracy of calibration by the potentiometer method are a combination of those imposed by the accuracy of the potentiometer itself and the dead band of the recording instrument. The potentiometer method may be unsuitable for recorders having a wide dead band (that is, greater than 0·15 percent) because the combined errors may be unacceptable. A dead band width of 0·15 percent of scale span is acceptable.

B-11. CALIBRATION OF TEST INSTRUMENT BY MILLIVOLT SOURCE

B-11.1 A standard laboratory source is used for this purpose in lieu of the potentiometer and the standard cell. The procedure to be followed is similar to that in **B-10.1 to B-10.7.**

B-12. CALIBRATION AND MAINTENANCE OF TESTING INSTRUMENTS OFF SITE

B-12.1 Routine calibration of temperature recorders should be carried out with a potentiometer and standard cells designed for the purpose. The instruments should be re-calibrated by the makers or by an appropriate standards laboratory at six-monthly or at closer intervals, as suggested by the manufacturers.

B-12.2 Routine checking of accuracy of the test pressure gauges should be carried out by a recognized testing laboratory.

B-12.3 Maintenance of temperature recorders should be carried out in accordance with the makers instructions and should be followed by recalibration as recommended by them.

B-13. CALIBRATION OF INSTRUMENT ON SITE FOR TEST PURPOSES

B-13.1 The following procedure has been found satisfactory:

a) Calibrate the test instrument and one of the thermocouples by the oil bath method given in B-9.1 to B-9.5 at the sterilizer temperature expected prior to arrival on site. Ideally, this should be undertaken in similar ambient conditions to those expected on site. Adjust recorder as required.

b) Check this calibration with a millivolt source as described in B-11.1 and note the indicated temperature difference from that obtained with the oil bath. This is the thermocouple error which should be noted.

c) At site, apply millivolt source to recorder and check the reading obtained previouslv as a check on the recorder and the millivolt source.

d) Connect all the thermocouples and expose the hot junctions of the bundle in the chamber space to check tracking of the group at the sterilizing temperature. The thermocouple error should be unchanged from that obtained off site.

e) If discrepancies are noted, it may be necessary to check individual calibration with the oil bath (on or off site) or check those thermocouples which produce anomalous readings.

NOTE -The use of the millivolt source at the beginning and the end of a series of tests produces a check &the continuing integrity of the instrumentation; similarly, the thermocouple bundle should be exposed to steam in the chamber to check 'tracking'.

B-13.2 Temperature errors are often observed when ungrounded thermocouples are placed in solutions in glass or plastic containers. These errors occur most frequently when water is the heating medium. In this situation, the solution in the container and the measuring junction should be insulated from ground. Grounding the thermocouple junction will usually eliminate this error. In some sterilizer measurement applications, it is a common practice to ground all thermocouples.

B-13.3 The following points should be taken care of for thermocouples on PPM programme and for validation of the instrument and sterilizing cycles:

a) Select the proper thermocouple wire for the application. Wire of the proper size, grade and type of insulation is required, for accurate reading.

b) Choose a measuring unit (potentiometer, etc), which is appropriate to that sterilizing instrument and appropriate for the application; and do not use it outside its limits.

c) Check the calibration of the measuring system before and after the validation tests and calibrate the system in accordance with the requirements.

d) Use single unbroken lengths of wire from measuring juction to potentiometer. When this is not possible, locate connectors in an environment of constant ambient temperature.

e) Check the measuring junction (that is, its size and arrangements) so that the conditions of constant temperature exist for a short distance away 'from the junction along both thermocouple wires.

f) Track down and correct errors in thermocouples during calibration, checking before beginning validation and PPM. Zeroing out errors may satisfy a calibration requirement but may lead to problems during testing programme and PPM.

g) Protect the measuring junction and lead wire against physical abuse. Straining and sliding with accompanying cold working will change thermocouples' thermoelectric power and may lead to errors of temperature gradient.

h) Keep a long of calibration and measurement activities as well as problems and their solutions.

j) Make required repeated calibration and prevalidation tests prior (and with PPM) to validation.

APPENDIX C

(Clause 2.5)

PLANNING INFORMATION

C-l. GENERAL

C-l.1 Information given in this appendix is intended as a general guide for initial planning purposes. There are wide variations between actual dimensions, weights and service requirements of different makes of sterilizers. The actual requirements of the machines to be installed should be established before detailed planning is undertaken because they can differ widely from manufacturer to manufacturer for a given size of sterilizer.

C-1.2 The provision of adequate clearance around machines, giving access for maintenace, is essential. Not less than the minimum clearance should be provided in all cases although some manufacturers may claim that smaller clearances are permissible. The minimum clearance should be 900 mm around all parts to which access 'for routine maintenance is necessary (see Fig. 5 and Table 13).

C-1.3 Particular care should be taken to ensure that sufficient clearance is allowed for large items, such as vacuum pumps, to be withdrawn from the sterilizer frames.

C-1.4 Attention is drawn to the need for adequate ventilation of the area near the sterilizers to remove the heat emitted. The values in Table 14 are for guidance only.

C-l.5 Service pipework, for example, steam and water pipes, should not be installed over the top of a sterilizer but kept to a wall away from the sterilizer. The run-outs to individual sterilizers should be at high level. Additional head room may be required with this arrangement to permit removal of a sterilizer without disturbance of the fixed pipework.

C-l.6 Some useful information in connection with the design of services for sterilizers is given in Table 15.

C-2. MINIMUM PLANNING DIMENSIONS

C-2.1 The following notes refer to Fig. 5 and to Table 13 below:

a) Dimension *B* does not include the projecting parts associated with sideways sliding doors. In most cases, such projections are confined to the front end of the machine and can be accommodated within the recommended dimension *A* without impeding access for maintenance.

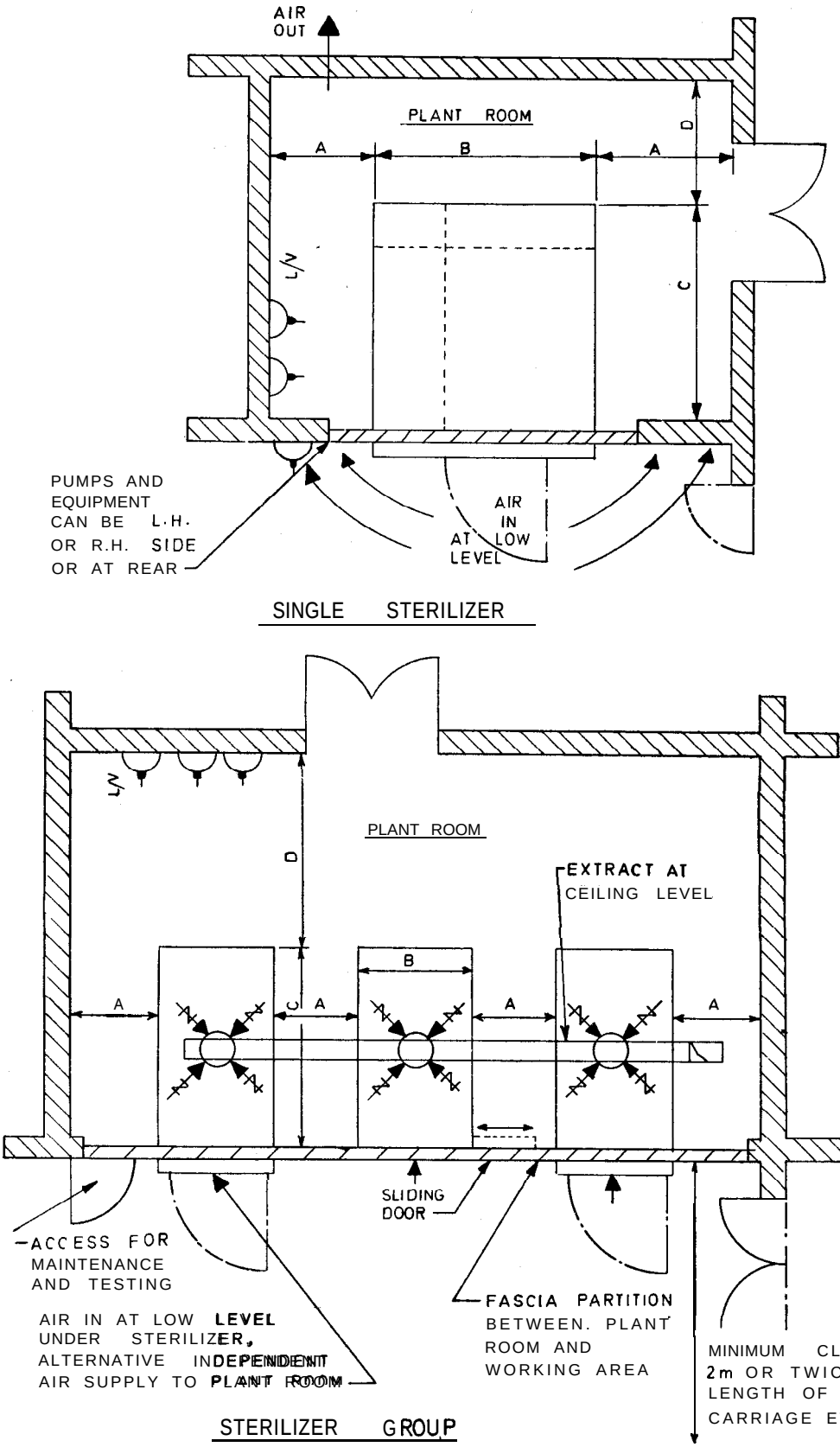


FIG. 5 TYPICAL PLANNING DIMENSIONS (Not to Scale)

TABLE 13 MINIMUM PLANNING DIMENSIONS FOR TYPICAL SIZES OF STERILIZERS

(Clauses C-1.2 *and* C-2.1)

Type of Sterilizer	Size mm	Nominal Capacity Litres	Dimensions as in Fig. 5 mm					Weight (Total) kg	Portage for Installation / Removal (Nominal)	
			*A**	*B*	*C*	*D*	Height		Minimum Dimensions	Weight† kg
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
Porous loads	660 dia x 760‡	280	900	1 300	1 ooog	3 000	2 600	2 040	1'3 x 1·0 x 1·5	1 000
	660 x 660 x 660	300	900	1 100-1 200	1 500	1 000	2 200	600-l 500	2'0 x 1'0 x 1·5	600-l 500
	910 x 660 x 660	400	900	1 400	1 700	1 000	2 200	650-l 800	1'9 x 1'0 x 1'5	650-l 800
	910 x 660 x 990	600	900	1 400	2 100	1 000	2 200	1 100-I 800	2'0 x 1'5 x 2·2	1 000-l 800
	910 x 660 x 1 320	800	900	1 400	2 100	I 200	2 200	1 100-1 600	1·8 x 1'4 x 2'0	950-I 600
Bottled fluids	910 x 660 x 660	400	900	1 200-1 400	1 700	1 000	2 100	650-l 800	2·1 × 1·6 x 1·9	650-l 650
	910 x 660 x 990	600	900	1 900	1 700	1 000-1 500‖	2 100	1 100-2 000	2'1 x 1·5 x 2'3	900-1900
	910 x 660 x 1320	800	900	1 900	2 400	1 000-1 500‖	2 100	1 100-2 100	2'1 x 1·5 x 2'6	950-2 000
	910 x 660 x 1600	970	900	1 600	2 300	1 000	1 800	2 540	2·0 x 1·2 x 2'4	
Unwrapped instruments and unwrapped utensils	300 dia x 500	35	600	690	900	900	1 800	350	Not normally broken down	
	510 dia X 510	100	900	1 000	1 000	I 000	I 900	450		
	450 dia x 760	130	900	1 000	1 500	1 000	1 800	400-700		
	510 dia X 910	180	900	1 000	1 700	1 000	2 000	550		
	510 x 510 x 910	240	900	1 000	1 700	1 000	I 900	750		

*Dimension 'A' should include provision for a sliding door (where appropriate), typically chamber width plus 450 **mm.**

†There **may be considerable variation in weight, depending upon the manufacturer.**

‡The **figures 660 dia** x 760 relate to vertical chamber machine.

§**Excluding** tracks for containers for vertical chamber machine.

‖**This dimension includes the width of compressor plus 600 mm clearance between the wall and the sterilizer.**

b) The minimum working height required for maintenance is 2 700 mm above floor level.

c) The dimensions quoted are also applicable to free standing units if allowance is made for the casing.

d) Extra allowance must be made for built-in or free standing steam generators when these have to be provided in addition.

e) Spacing should be such that it is possible to replace any sterilizer without disturbing others in the same installation. In some cases, this will entail an increase in dimension *D*.

f) The building and room access doors should be of a type and size which will permit passage of the equipment.

g) A single door will be required in the front panel if there is no other direct route between the plant room and the front of the sterilizer(s).

h) When sterilizers with vertical sliding doors are used, the height of the base of the chamber above finished floor level is usually higher than with machines having hinged or horizontally sliding doors.

j) Break tanks, as may be required in 7.6.1, are not shown in these drawings.

k) Fire compartmentations should be considered.

TABLE 14 HEAT EMISSION FOR ALL TYPES OF STERILIZER

(Clause c- 1.4)

SIZE	NOMINAL CAPACITY	HEAT EMISSION (AVERAGE) TO SURROUNDINGS AT 20°C (EXCLUDING EMISSION FROM LOAD)		
		Heat Emission to User Space	Heat Emission to Plant Room	Total Heat Emission
(1)	(2)	(3)	(4)	(5)
mm	litres	kW	kW	kW
10 dia x 510	100	0'5	1'5	2 0
450 dia x 760	130	0·5	1'5	2·0
510 did X 910	180	0·5	2'0	2·5
510 x 510 x 910	240	0'5	2·5	3·0
660 x 660 x 660	300	0'5	3'0	3'5
910 x 660 x 660	400	1·0	3.5	4'5
910 x 660 x 990	600	1·0	4·5	5'5
910 x 660 x 1320	800	1·0	6·0	7·0
910 x 660 x 1600	970	1'0	7'5	8'5

NOTE 1— The figures include emission from pipework fitted to the sterilizer but do not allow for excessive lengths of steam pipe manifold.

NOTE 2 — The total heat emission given is the maximum which might be expected. The proportion of heat emitted to the user space varies with the type and the make of machine. These figures should, therefore, be used as a guide only and the advice of the manufacturer should be sought.

NOTE 3 — The heat emission to the user space is given for a sterilizer with the door normally closed, if the door is left open for a significant time with the steam jacket pressurized, the heat emission to the user space will be considerably increased.

NOTE 4 — The heat emission to the user space is greatly reduced, and the heat emission to the plant room is correspondingly increased if the sterilizer door is mounted behind the fascia panel.

APPENDIX D

[Clauses 2.7, 2.9, 7.11.5, 9.1.2, 10.1.2, 10.2.2, 10.3, 10.4(d), 10.5.5, 10.15.1(b), 10.15.2, B-4.12, G-1.1, H-7.1, L-1.1, L-2.1, L-5.1 *and* M-l.1]

COMMISSIONING, OPERATION AND MAINTENANCE OF STERILIZERS

D-l. INTRODUCTION

D-l.1 It is of utmost importance that all sterilizers are both effective in reaching the performance required for sterilization of loads and safe in operation.

D-l.2 For assurance on these points, responsibilities rest variously with the contractor who installs the machine, and the sterilizer engineer. This appendix identifies duties and responsibilities of those concerned and describes the records which should be kept.

D-1.3 When a new installation is to be handed over in full working order, it is the contractor's duty to carry out the commissioning and to perform any demonstration which is necessary before the sterilizer may be accepted for use.

D-1.4 A consultant microbiologist normally exercises clinical responsibility in CSSD. It is current policy to recommend such oversight in any sterilizing unit.

D-2. DUTIES AND RESPONSIBILITIES

D-2.1 The Sterilizer Engineer

D-2.1.1 The person should have direct contact with the responsible consultant microbiologist and principal pharmacist for quality control in the region. His duties in respect of all sterilizers are as follows:

a) Advising on the choice of sterilizer in conjunction with the appropriate hospital staff advising upon the services requirements;

b) Advising on the contract details, including specification and drawings, and test loads for commissioning;

c) Acting as contract supervising officer (CSO) where so nominated, for the purpose of supervising the commissioning and acceptance tests in accordance with the contract requirements;

d) Supervising or executing annual performance tests;

e) Superivising or executing re-commissioning of a sterilizer after it has been withdrawn from service for the repair of a serious defect or for the statutory two-yearly inspection of pressure vessels, or for modification or for change of duty;

f) Examining the records of all other periodical tests, faults and unscheduled maintenance and advising, where necessary, on any action which appears to be required as a result;

g) Certifying, after action as in (d) or (e) above, that the performance complies with that specified when the sterilizer was ordered and with any subsequently agreed variations, and approving, in agreement with the microbiologist and the operator, that the sterilizer is fit for service after such tests;

h) Advising the operator upon the application of master temperature record(s) [MTR (s)] to particular sterilizers/processes and the interpretation of such records;

j) Advising upon the content of the maintenance schedules applicable to each sterilizer;

k) Advising upon any sterilizer maintenace contract and on the general procedure to be adopted for calling the manufacturer's service engineers in emergencies;

m) Confirming the proper engineering records arising from all commissioning and routine tests and checks are kept for each sterilizer;

NOTE — The form and contents of the records should be agreed between the sterilizer engineer, and the operator. In the case of sterilizers used in the processing of medicinal products, the form of these records should also be agreed by both (*see* D-2.3).

n) Examining the plant history records and confirming that the agreed periodic testing and maintenance procedures. have been undertaken;

p) Advising the operator in conjunction with the contractor and the maintenance engineer upon the method of operating the sterilizer;

q) Advising on which types of faults are to be considered as serious (see D-8.7.3).

r) Establishing liaison with the maintenance engineer and the operator to ensure the continuing satisfactory performance of the sterilizers, including engineering advice on specific problems, such as wet loads on porous load sterilizers;

s) Supervising maintenance tasks and tests, ensuring that faults are rectified, and seeking the assistance of the operator where necessary;

NOTE — Maintenance will include cleaning the door joints and seals when these are not readily accessible to the operator.

t) Responsibility for the upkeep of the plant history record and ensuring that the records are kept on the approved test report forms;

u) Executing quarterly and half yearly tests;

NOTE — These may, if mutually convenient, be undertaken by the operator.

v) Co-operating with the operator upon the method of operating the sterilizer;

w) Establishing liaison with the operator to ensure the continuing satisfactory performance of the sterilizers;

NOTE — This will include approving, in advance, all the procedures for calling in the manufacturer's service engineers in emergencies .

x) Reviewing weekly, together with the operator, the sterilizer performance and records for the previous week, comparing all temperature recorder charts (TRCs) with the MTRs and investigating the cause of any abnormality;

y) Holding all keys required for access to or control of the sterilizers, except those necessary for the operation of the sterilizers, and the duplicates of the keys necessary for the operation of the sterilizers; and

z) Issuing maintenance certificates for each sterilizer at agreed intervals to the operator.

D-2.2 The Operator

D-2.2.1 The duties of the operator are as follows:

a) Reporting to the engineer any breakdown of sterilizing plant which may affect the hospital service;

b) Agreeing on the operating procedure with the sterilizer engineer and establishing liaison with him to ensure the continuing satisfactory performance of the sterilizers;

c) Reporting to the engineer immediately if there is any malfunction or suspected malfunction of a sterilizer, including;

1) A failure to satisfy any approved routine test (such as the Bowie/Dick tape test for porous load sterilizers),

2) Any accident or incident involving the machine, and

3) Any other feature of a sterilizer performance or behaviour which suggests that something may have happened to cause a change from the established normal behaviour of the machine.

d) Co-operating with the maintenance engineer to ensure that sterilizers are made available for routine maintenance and periodic testing;

e) Examining, at least daily, all TRCs and comparing them with the MTR for the sterilizer;

f) Supervising the use of the sterilizer processing log (see D-8.8.1 to D-8.8.5);

g) Ensuring that the daily maintenance tasks are carried out;

h) Reviewing weekly, together with the maintenance engineer, the sterilizer performance and the records for the previous week and comparing all TRCs with the MTRs, assisting as necessary in the investigation of the cause of any abnormality;

j) Holding those keys necessary for the operation of the sterilizers, as agreed with the engineer;

k) Ensuring that sufficient forms, charts or record books, other than those held by the engineers, are readily available since no machine may be operated without a record of performance being kept;

m) Ensuring the satisfactory performance of the daily Bowie/Dick tape test for each porous load sterilizer, examining the result and authorizing the use of the sterilizer, if appropriate;

n) Witnessing the leak rate test for each porous load sterilizer;

p) Ensuring that he or she is in possession of a valid maintenance certificate for each sterilizer in use (see D-6.1) ;

q) Operation of the sterilizer, including the following:

1) Normal housekeeping procedures and those daily maintenance tasks on the sterilizer which are appropriate for an operator to carry out, such as cleaning the chamber, the chamber drain, the door joints and seals (where these are readily accessible to the operator), removing broken glass, labels and debris;

NOTE — These tasks should be scheduled by the operator and agreed upon with the sterilizer engineer.

2) Exchanging charts on chart recorders and replenishing ink;

3) Completing entries in the sterilizer processing log and on TRCs;

r) Ensuring that no sterilizer load is released for use until the relevant records have been checked and approved; and

NOTE — These records will include the TRC when a recorder is fitted and, where relevant, the appropriate entries in the sterilizer processing log.

s) Ensuring compliance with the procedure required in relation to the manufacture of pharmaceutical products.

u-3. DOCUMENTATION AND PROCEDURES

D-3.1 In the context of this document, a batch is defined as the contents of one load of a sterilizer.

D-3.2 In order to comply with necessary standards, the hospitals should keep records which provide assurance that the staff is performing duties in a satisfactory manner.

D-3.3 The records to be kept vary for the type of sterilizer in use and should include:

a) Commissioning data, including MTR charts which should be used as the standard for each batch;

b) Insurance surveyor's report (not applicable to hot air sterilizers);

c) Maintenance contract (where applicable);

d) Maintenance certificate;

e) Plant history record;

f) Sterilizer processing log for the following:

1) Sterilizers processing medicinal products (both steam and hot air sterilizers); and

2) Porous load sterilizers.

D-4. COMMISSIONING DATA

D-4.1 This data should be prepared and kept by the sterilizer engineer but, where appropriate, provision should be made in the contract documents for the test results to be prepared and provided by the contractor in a form suitable for incorporation in the commissioning data. A duplicate should be held by the maintenance engineer and kept in association with the plant history record.

D-4.2 The sterilizer should be inspected and tested to establish whether it complies with the various requirements of the contract specification, including the relevant requirements of Indian Standards where these are called for in the specification. The data to be recorded should include:

a) Results of the inspection and/or test for each of the specification requirements;

b) Such records as are necessary to demonstrate that the sterilizer is capable of performing satisfactorily with each batch size and the type of load for which it was ordered;

NOTE — This will require the conduct of fully-instrumented tests but will not necessarily entail a separate test for every variation of loading condition. The tests which are necessary in each case should be determined as follows (*see also* D-4.5):

1) For sterilizers to be used for'processingmedicinal products., jointly by the sterilizer engineer, and the quality controller; and

2) For all other sterilizers, by the sterilizer engineer in association with the consultant microbiologist;

c) **Records showing correlation between** the **performance of the instruments fitted** on the sterilizer and the test instruments used for commissioning; and

d) Records showing correct functioning of the control equipment, such as temperature controllers, timers, air detectors, load simulators, signal lights and indicators.

D-4.3 The commissioning record should indicate satisfactory tests on safety devices, as appropriate, safety valves on jacket and chamber; for example, door interlock preventing opening of the door until temperature has fallen to a safe level; door interlock preventing entry of steam until door is properly secured; door interlock preventing unauthorized opening of the door after an unsatisfactory sterilization cycle.

NOTE — It may not be practical at present to equip some sterilizers with mechanical interlocks to prevent the doors or lids opening with the loads at an unsafe temperature or when the sterilization cycle has not been satisfactorily performed. These additional safety devices should be fitted as soon as it becomes practicable to do so; meanwhile, operating instructions should be in terms to ensure safe operation.

D-4.4 When correlation is accepted between the sterilizer TRC and the multi-channel commissioning recorder, the TRC is to be marked 'MASTER TEMPERATURE RECORD' (MTR). Each MTR and the corresponding chart from the multi-channel recorder is to be cross-referenced and endorsed as follows:

a) Sterilizer plant reference number;

b) Description of load (for example, 500 ml bottles of saline);

c) Distribution pattern of load;

d) Confirmation that all monitor bottles, or items of equipment in the load, reached the required temperature and were maintained at this temperature for the necessary time;

e) Description and distribution pattern of other types and sizes of load, if any, for which the MTR is to be accepted as valid;

f) When the load comprises bottled fluids, the point during the cycle at which the load temperature had fallen to 80°C and the temperature interlock on the door opening machanism was released;

g) Signature of sterilizer engineer and date; and

h) Signature of operator and date.

D-4.5 A sufficient number and variety of MTRs should be prepared so that for each loading condition (that is, for each batch type and size and each type of equipment to be sterilized), there is a suitable MTR available. In many cases, the design of the sterilizer and/or the nature of the items to be sterilized will enable worst case loading conditions to be established or predicted with reasonable certainty, and thus allow one MTR to be used for several loading conditions. Particular care is necessary with respect to certain products, such as some solutions, which are subject to decomposition when heated. In these cases, the shape of the MTR must be such that it not only ensures certainty of sterilization but also it does not permit the product to be exposed to high temperatures for so long that unacceptable degradation occurs. The number of MTRs which are necessary in each case and the particular loading condition(s) for which each MTR is suitable should be determined as follows:

a) For sterilizers to be used for processing medicinal products, jointly by the sterilizer engineer, and the quality controller;

b) For hot air sterilizers not processing medicinal products, jointly by the sterilizer engineer and the operator; and

c) For all other sterilizer, by the sterilizer engineer.

D-4.6 A copy of each MTR for all machines processing medicinal products and for hot air sterilizers must be supplied for daily reference by the operator and should be kept with the sterilizer processing log. Ideally, it should be reproduced in transparent form so that it can be laid over the TRC for comparison purposes.

D-4.7 When it is accepted that the sterilizer has been correctly set up and is working satisfactorily, a record should be made of all the significant details of a normal cycle under automatic control. The cycle should be performed with a standard *test* load in the chamber, details of which should be recorded. In the case of porous loads machines, a standard single pack test load of the type used for Bowie/Dick and thermocouple tests should be used. Observations should also be made of details of each stage and sub-stage of the cycle such as the time taken, the number of pulses, temperatures, pressures and levels of vacuum at all significant points during the cycle. For example, at'the end of each stage or sub-stage.

D-4.8 The commissioning data for porous load machines should include records of performance tests on the vacuum system as follows:

a) Maximum level of vacuum achieved during the leak rate test;

b) Maximum acceptable leak rate specified for the machine, against which it should be tested;

c) Actual leak rate measured during the leak rate test; and

d) Vacuum level(s) achieved during the vacuum stage(s) should be included amongst the data to be recorded during the cycle as required by D-4.7.

D-5. MAINTENANCE CONTRACT

D-5.1 Where applicable, a copy of any sterilizer maintenance contract should be held by the maintenance engineer.

D-6. MAINTENANCE CERTIFICATE

D-6.1 The engineer should certify to the operator, at agreed fixed intervals, that the necessary schedules of maintenance tasks have been satisfactorily completed. A detailed entry should have been made in the plant history record. Provided it is compiled and endorsed in a suitable manner and kept where the operator has free access to it, the plant history record may be used to perform the function of the maintenance certificate.

D-7. PLANT HISTORY RECORD INCLUDING RECORD OF MAINTENANCE AND PERIODIC TESTS

D-7.1 The engineer should be responsible for this document but, where appropriate, it may be combined with the sterilizer processing log; in such cases, the two separate parts of the combined document should be clearly identified.

D-7.2 The document should carry plant reference number for the individual sterilizer and the date of installation and commissioning. It should contain records of all performance tests, irregularities in performance and modifications to the sterilizer. It should also record all maintenance work, both scheduled and unscheduled, and show that the examinations, tests and checks have been carried out as cited in the sterilizing plant section. It should be noted, however, that the maintenance schedules in these manuals may need to be modified to suit a particular sterilizer, in accordance with the maintenance schedules recommended by the manufacturer or as the result of experience. Such variations should be noted in the plant history record.

D-7.3 The engineer should sign and date, at least weekly, all entries relating to maintenance, both scheduled and unscheduled.

D-7.4 The operator should countersign weekly that he has seen the entries, indicate whether he is satisfied with them and comment, where appropriate. In the case of sterilizers processing medicinal products, the quality controller should examine, sign and date the record weekly, or at intervals to be agreed locally.

D-7.5 Records for entry in the plant history record should include those detailed in the following clauses.

D-8. DATA FOR SETTING AND TESTING

D-8.1 All the data necessary for setting and testing the sterilizer should be summarized and presented in a convenient form for reference, including that derived from manufacturing information and from commissioning and subsequent performance tests.

D-8.2 Weekly Record

D-8.2.1 This should include as appropriate to the type of sterilizer:

a) Records of tests carried out on automatic process control system. These records should be made during a normal cycle under automatic control, the chamber being loaded as it was for the commissioning test at D-4.4 and should include:

lj Records of indicating thermometer, TRC and pressure gauge readings under 'steady state' conditions during the sterilizing stage;

2) Records of details of each stage and sub-stage of the cycle, such as the time taken, number of pulses, temperatures, pressures and levels of vacuum at all significant points during the cycle such as the change from each stage or sub-stage to the next; and

3) Record of the results of investigation into the reasons for any deviation from their normal values of any of the parameters recorded.

b) Confirmation that all TRCs have been examined and by whom;

c) Leak rate test results, including the level of vacuum achieved as well as the rate of leakage into the chamber;

d) A statement of the maintenance tasks carried out during each week and whether these have been completed satisfactorily; and

NOTE — The tasks need not be detailed in full; identification of the relevant task schedules by, for example, weekly or quarterly will suffice, exceptions only being detailed.

e) Confirmation that the door seal has been examined and is satisfactory.

D-8.3 **Quarterly Record**

D-8.3.1 Records of quarterly tests which, subject to discretion of the sterilizer engineer, should repeat the commissioning tests except that they may be made with an instrument with a minimum of 3 channels instead of a 12-channel chart recorder as used during commissioning.

D-8.3.2 In the case of fluids sterilizers, one batch type and size only need be tested but the various batch types and sizes should be tested in rotation at subsequent quarterly tests.

D-8.3.3 The record should include the results of the air detector performance test for porous load sterilizers and any load simulator test for sealed fluids sterilizers.

D-8.3.4 There are no quarterly tests on hot air sterilizers.

D-8.4 **Half-Yearly Record (For Hot Air Sterilizers Only) —** Records of tests on hot air sterilizers which, subject to the discretion of the sterilizer engineer, should repeat the production lod test.

D-8.5 **Yearly Record**

D-8.5.1 Records of annual performance tests which, subject to the discretion of the sterilizer engineer, should repeat the commissioning tests.

D-8.6 **Records as Required**

D-8.6.1 A record of faults and unscheduled maintenance should be kept (see D-8.7.1 to D-8.7.3).

D-8.6.2 A record of modifications to the sterilizer should be kept [see D-2.1.1 (e)].

D-8.6.3 A record of re-commissioning tests should be kept which should repeat some or all of the commissioning tests. The particular tests which are appropriate in each case should be determined as in D-4.5. In the case of sterilizers processing sealed fluids for which MTRs have previously been established, re-commissioning tests need only be performed for two batch/contents sizes*. The two test loads should be distinctly dissimilar, for example, 1 litre bottles and 20 ml bottles (or the largest and smallest bottle sizes regularly processed). The following circumstances will indicate the need for re-commissioning tests to be carried out:

a) When a machine has been moved and re-installed at a new site (not applicable to portable 'bench top' machines);

b) When a machine has been withdrawn from service for the repair of a 'serious' defect (see D-8.7.3);

c) When a machine has been subjected to the statutory two-yearly inspection of pressure vessels;

d) When a machine has been overhauled or modified;

e) When there is a change to a cycle or type of load for which no suitable MTR is available, such as the introduction of a new loading pattern, a new type of load, a change in container volume or a change in batch size;

f) When there is a significant change in the pattern of the TRC from that of the MTR;

NOTE — If there is any doubt about whether a change is significant, the advice of the sterilizer engineer should be sought. In the case of machines processing sealed fluids, any change in the time of stage 1 (heat up) or stage 2 (sterilizing) of the sterilizer cycle by more than 3 minutes from that shown on the MTR should be regarded as significant.

g) When there is a demand for re-commissioning by an authorized inspectorate; and

h) When the sterilizer engineer considers re-commissioning to be necessary.

NOTE — The advice of the sterilizer engineer about whether re-commissioning is necessary should be sought when there is any replacement of a component or alteration or adjustment affecting the steam pressure, operational pressure or temperature setting or cycle timing or when there has been a replacement or adjustment affecting the continuous discharge rate of the chamber drain, where this is possible.

*A complete range of new MTRs will be required if the two batch tests reveal significant changes in the MTRs.

D-8.6.4 Each record as in D-8.3.1, D-8.4, D-8.5, D-8.6.2 and D-8.6.3 should include a statement of the fitness for use and be signed and dated as following:

a) For annual tests, for re-commissioning tests and for modifications, by the sterilizer engineer; and

b) For quarterly and half-yearly tests between the annual tests, by the sterilizer engineer or the operator.

D-8.7 Fault Procedures and Records of Faults

D-8.7.1 Any fault found by the sterilizer engineer or the operator should be recorded in the plant history record.

D-8.7.2 If the sterilizer engineer or the maintenance engineer finds a fault, he should inform the operator forthwith.

D-8.7.3 If a serious fault occurs, the sterilizer should be withdrawn from service and should not be used for the production of sterile materials until it has been approved for re-use jointly by the sterilizer engineer and the operator. The sterilizer engineer should advise, for each type of sterilizer as to which types of faults are to be considered as serious. The list should include all faults. which may result in failure to sterilize or danger to personnel or damage to the product. In the case of faults not classified as serious, the machine may be taken back into service immediately after rectification of the fault and on satisfactory completion of the tests; listed as weekly tests in Appendix F.

D-8.7.4 Details of remedial action and subsequent performance checks should also be recorded. These entries should be signed and dated by the engineer and should be countersigned by the operator before the machine is returned to service.

D-8.8 Sterilizer Processing Log: General Requirements

D-8.8.1 The operator should be responsible for this document but, where appropriate, it may be combined with the plant history record; in such cases, two separate parts of the combined document should be clearly identified.

D-8.8.2 The entries as in D-8.8.4 or D-8.8.5 below should be made, where relevant, by the operator for each load sterilized, and the log should be countersigned weekly by the engineer to indicate that he has seen it.

D-8.8.3 At the commencement of each working day, the readings on the cycle counter should be recorded in the processing log (or *in* the plant history record where a processing log is not required). The thermometer and pressure gauge reading during the sterilizing stage of the first cycle in the data should be similarly recorded.

D-8.8.4 The sterilizer processing log for medicinal products, whether the machine is of the steam or the hot air type, should include:

a) Product title and batch. size, or description of load;

b) Batch number;

c) Sterilizer cycle number;

d) Indicating thermometer, TRC and pressure gauge readings at steady state during the sterilizing stage;

e) Time at sterilizing temperature (determined from TRC);

NOTE — It is the duty of the operator to ensure **that (a) to (e) are properly completed for each batch.**

f) An entry in respect of each batch, signed and dated by the operator stating whether the TRC matches the MTR for the batch or product;

g) Details as in (a) to (f) above need not be recorded separately if they are already recorded in a batch manufacturing record; the sterilizer engineer requires access to these records;

h) An entry, signed and dated by the quality controller at least weekly, confirming that he has examined the entries for the week in both the plant history record and the sterilizer processing log or batch manufacturing record and stating whether he is satisfied with them;

j) An entry, signed and dated by the engineer at least weekly, to acknowledge that he has seen the entries; and

k) The TRC, marked to link unambiguously with the sterilizer serial number and, for each cycle, the product title, batch size or description of load, batch number and sterilizer cycle number.

NOTE — The TRC should be signed and dated either by the operator or by the quality controller to confirm that it matches the MTR and that the loading pattern was the same as that specified on the MTR. A separate chart for each cycle is preferred.

D-8.8.5 The sterilizer processing log for porous loads should include:

a) The daily Bowie/Dick tape test result;

NOTE — The test sheet should be marked to show the sterilizer serial number, sterilizer cycle number, data and signature of the operator. The sheet should also be marked to identify it with the corresponding entry in the processing log.

b) An entry signed by the operator stating whether the TRC for each load is satisfactory;

NOTE — The TRCs should each be marked to identify the sterilizer, cycle number(s) and date. A separate chart for each cycle is not required. The record should be clearly marked to show any TRC relating to any unsatisfactory cycle. The record must include details of any load which is automatically rejected as non-sterile.

c) An entry signed by the operator to confirm that he has seen all records made in the plant history record during the week and indicating whether he is satisfied with them; and

NOTE — The entries should include the results of the weekly temperature and automatic control rest, including vacuum levels.

d) **An entry, signed** and dated by the engineer to confirm that he has examined the details in the log at least weekly, and that the daily Bowie/Dick and TRCs compare satisfactorily with the temperature record obtained during commissioning.

D-8.9 **Retention of Records**

D-8.9.1 For pharmaceutical products, records should be kept as required by the Government regulations or, if not specified, records relating to the process, including the sterilizer processing log, TRCs and Bowie/Dick tape test sheets, should be kept for at least twelve months.

D-8.9.2 Records relating to the plant, including commissioning data, MTRs insurance surveyor's reports and the plant history records should be kept throughout the life of each sterilizer.

APPENDIX E

(Clauses 2.8, 7.11.1 and 7.11.3)

CHECK-LIST OF PRE-COMMISSIONING PROCEDURES

E-I. **CHECKS OF ADEQUACY OF ENGINEERING SERVICES AND OF GENERAL ENGINEERING PERFORMANCE OF STERILIZER**

E-l.1 The sterilizer has been provided and installed in accordance with the specification and the drawings.

E-1.2 Tests have been satisfactorily completed on all the services provided by the services contractor or sub-contractor.

E-1.3 The electrical equipment on the sterilizer has been provided, installed, connected and tested, and is acceptable.

E-1.4 The noise and vibration levels during operation are acceptable.

E-1.5 There are no leaks of steam, water, air or effluent at any temperature or pressure within the working range.

E-l.6 All supports, bases and fixings are rigid and secure, and without imposed strain from pipework connections.

E-l.7 When the sterilizer appears to be functioning in a proper manner, there is no evidence of interference with the performance of other equipment connected to the same services or of unsatisfactory operation of existing drainage services.

E-2. TESTS OF PERFORMANCE OF STERILIZER MECHANICAL AND ELECTRICAL FUNCTIONS (INCLUDING SAFETY DEVICES) UNDER WORKING **CONDITIONS**

E-2.1 Steam, water and air supply pressures during the full cycle of operation are satisfactory.

E-2.2 Drains effectively remove effluent when all plants in the vicinity, including the sterilizer, are connected.

E-2.3 There is no adverse effect of the full operation of all services on other connected plants in the vicinity.

E-2.4 Safety devices ensure the following:

a) Doors are locked before the admission of steam,

b) Doors cannot be unlocked when under internal pressure greater than 0·2 bar,

c) Steam valve closes on failure of power supply (simulated), and

d) Chamber is vented to atmosphere during the opening of the door via the door opening and before the securing mechanism is fully released.

E-2.5 The interlock between manual and automatic control allows only one system to be used at one time.

E-2.6 Operation of an automatically controlled sterilizer ensures that it meets the specification requirements as set out in the manufacturer's operating details.

E-2.7 Operation nf a manually controlled sterilizer ensures that it meets the specification requirements as set out in the manufactuier's operating details.

E.2.8 During each stage of the operating cycle,

the controls react correctly and safely under the following conditions:

a) Low steam pressure,
b) Low water pressure,
c) Incorrect vacuum, and
d) Simulated power failure.

E-2.9 Operation and readings of all instruments appear satisfactory, including return to zero*.

***This may not be achievable with combined pressure and vacuum gauges.**

E-2.10 Calibration of all instrumentation and controllers is satisfactory.

E-2.11 Temperature of exposed surfaces of the sterilizer, including all valve handles and door operating gear does not exceed the ambient temperature by more than 20°C.

E-2.12 Loading trolleys or other aids are effective in use.

APPENDIX F

[*Clauses* 2.10, 7.11.1, 8.1.1, 8 1.2, 10 2.1(a), 10 6.1, 10.15.1(a) *and* D-8.7.3]

SUMMARY OF STERILIZER PERFORMANCE TESTS

F-1. PERFORMANCE TESTS

F-1.1 The Various Performance Tests are Given Below in the Tabular Form:

UNDERTAKEN BY	STERILIZER ENGINEER	OPERATOR	STERILIZER	STERILIZER ENGINEER BY LOCAL ARRANGEMENT	STERILIZER ENGINEER BY LOCAL ARRANGEMENT	STERILIZER ENGINEER	STERILIZER ENGINEER
Frequency / Type of sterilizer	When commissioning and re-commissioning(a,b,c)	Daily(d)	Weekly(b,e)	Quarterly(e)	Half-yearly(e)	Yearly(e)	2-yearly, or yearly in certain cases(e)
Porous loads	(1) Perform weekly tests (*see* Appendices D, G, H and J) (2) Thermocouple test (using 3 thermocouples) (*see* Appendix G) (3) Air detector tests (*see* Appendix K)	Bowie/Dick tape test (*see* Appendix H)	(1) Temperature and automatic process control test (*see* Appendix G) (2) Bowie/Dick tape test (*see* Appendix H) (3) Leak rate test (*see* Appendix J)	(1) Repeat weekly tests (2) Thermocouple test (using 2 or 3 thermocouples) (*see* Appendix G) (3) Air detector function test (*see* Appendix K)	Repeat quarterly tests	(1) Repeat quarterly tests (2) Air detector performance test (*see* Appendix K)	Statutory inspection by competent person, in addition to yearly performance test(s)
Fluids	(1) Perform weekly test (*see* Appendices D and L) (2) Thermocouple test (using 11 or 12 thermocouples) (*see* Appendix L)	Nil	Temperature and automatic process control test (*see* Appendix L)	(1) Repeat weekly test (2) Thermocouple test (using 3 thermocouples) (*see* Appendix L)	Repeat quarterly tests	(1) Repeat weekly tests (2) Thermocouple test (using 11 or 12 thermocouples) (*see* Appendix L)	
Unwrapped instruments and utensils	(1) Perform weekly test (*see* Appendices D and M) (2) Thermocouple test (using 3 thermocouples) (*see* Appendix M)	Nil	Temperature and automatic process control test (*see* Appendix M)	Thermocouple test (using 2 or 3 thermocouples) (*see* Appendix M)	Repeat quarterly test	Repeat quarterly test	
Hot air sterilizers	Thermocouple test(s) (usually using 12 thermocouples) (*see* Appendices D and N)	Nil	Nil	Nil	Thermocouple test(s) (using 3 thermocouples) (*see* Appendix N)	Thermocouple test(s) (usually using 12 thermocouples) (*see* Appendix N)	Nil

a) Tests on completion of installation of a machine by a contractor will be carried out by the contractor under the supervision of the sterilizer engineer.

b) These tests must also be carried out after unscheduled maintenance under certain circumstances (*see* **D-8.6.3** and **D-8.7.3**).

c) The sterilizer engineer has some discretion on the test conditions to be applied (*see* **D-4.2, D-4.5, D-8.3.1, D-8.3.4, D-8.4, D-8.6.1** and **D-8.6.3**).

d) Readings of temperature and pressure during sterilizing stage of first daily cycle (not the 'warm-up' cycle) should be recorded in processing log (*see* **D-8.8.3**). Cycle counter reading should be similarly recorded. Temperature and pressure at steady state are to be recorded in processing log for each batch of medicinal products.

e) These tests should be performed in association with and on completion of PPM tasks.

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APPENDIX G

[*Clauses* 2.8, 2.10, 7.11.3 nnd 8.1.3 (a)]

PERFORMANCE TESTS FOR POROUS LOAD STERILIZERS

G-1. GENERAL

G-1.1 The tests required are those referred to in Appendix D, the records of which are required for day-to-day production control purposes. They are as follows:

a) Bowie/Dick tape test (see Appendix H);
b) Leak rate test (see Appendix J);
c) Temperature and automatic process control test;
d) Quarterly tests;
e) Yearly, commissioning and re-commissioning tests; and
f) Air detector performance test (see Appendix K).

G-1.2 For all these tests, except at (b), the sterilizer should be loaded with a test casket or pack containing about 30 freshly laundered and aired towels as for the Bowie/Dick tape test. They should be carried out after a warming-up cycle has been performed (or otherwise in accordance with the manufacturer's instructions).

G-l.3 The Bowie/Dick tape test and the leak rate test are complementary.

G-l.4 Machines which satisfactorily pass these tests are deemed to be capable of sterilizing all porous loads. Packaging and loading and operating procedures must be devised which will enable the sterilizer to process 'difficult' loads in a satisfactory manner, for example, by extending the drying time.

G-2. WEEKLY TEMPERATURE AND AUTOMATIC PROCESS CONTROL TEST

G-2.1 This test may be performed simultaneously with the daily Bowie/Dick tape test where this is possible without contravening any of the essential test conditions.

G-2.2 The sterilizer should be operated under automatic control and the complete test cycle should be observed. At least three readings of chamber temperature and pressure should be taken from the sterilizer instruments at equal time intervals during the sterilization hold time. A record should be made in the plant history record of all these observations, and this should also include details of each stage or sub-stage of the cycle, such as the time taken, the number of pulses, temperature, pressure and levels of vacuum at all significant points in the cycle, for example, at the change from each stage or sub-stage.

G-2.3 The test should be considered satisfactory if all the following requirements are met:

a) The TRC agrees satisfactorily with the MTR.

NOTE — This is not the MTR referred to for sterilizers, processing medicinal products which are required for production control purposes for checking individual batches but the record obtained during commissioing which is retained for checking performance.

b) The measured parameters are consistent with previously recorded test results.
c) The engineer observing the test does not detect any mechanical or other anomaly.
d) On completion of the test, the towels which comprise the test pack, or the contents of the casket, are sensibly dry.

G-2.4 A satisfactory Bowie/Dick tape test is required (see Appendix H).

G-3. COMMON REQUIREMENTS FOR QUARTERLY, YEARLY, COMMISSIONING AND RE-COMMISSIONING TESTS

G-3.1 Each quarterly, yearly, commissioning and re-commissioning test requires temperature measurements to be recorded by separate thermometric equipment, using a minimum of two thermocouples during two separate performance tests, that is a small load test and a full load test.

G-3.2 For each of these performance tests, one thermocouple should be placed in the chamber drain, within 100 mm of the exit from the chamber, and another at the geometric centre of the towels comprising the test pack, the wires being carefully arranged to prevent steam tracking along them.

G-3.3 The first test should be performed with the single test pack in the chamber.

G-3.4 For the second test, the chamber should be fully loaded with a supply of packs of laundered and aired cotton fabrics sufficient to fill the sterilizer to a density of about 160 kg/m^3 including the test pack which may be placed at any convenient position within the chamber.

G-3.5 The temperature and automatic process control test should be carried out in association with the first test, and observations should be made as described and recorded. It may be necessary to perform the leak rate test without the single test pack in the chamber.

G-3.6 The second test should be carried out on satisfactory completion of the first test.

G-3.7 The tests should be considered satisfactory if all the following requirements are met.

a) The temperature in the test pack is within the limits of 134 $^{+4}_{-0}$ °C during a continuous period of 3 minutes of stage 2.

b) During the last 2 minutes of this sterilizing hold' period, the temperature in the test pack and drain should be coincident within the accuracy limits of instrumentation.

c) The duration of stage 2 does not exceed 6 minutes.

d) The cycle is completed in not more than 30 minutes,

In the case of machines which are set to operate with an extended drying time, the drying stage only must be re-set for the purposes of this, so that the cycle is completed in not more than 30 minutes.

e) The packs are sensibly dry.

G-4. **YEARLY, COMMISSIONING AND RE-COMMISSIONING TESTS**

G-4.1 The minimum number of thermocouples which should normally be used is three — one in the chamber drain, one in the centre of the test pack and the other, for detecting superheat, fixed about 50 mm above the test pack.

NOTE — The thermocouple in the chamber drain. should be in contact with the condensate at the phase boundary condition. This may sometimes require deeper insertion than the recommended 100 mm.

G-4.2 The geometric centre of the test pack may not always be the most appropriate location for the 'load' thermocouple and additional thermocouples may be placed in the test pack, for example, in the upper and lower halves; the temperature indicated by any one of the load thermocouples. must be coincident with that indicated by the thermocouple in the chamber drain during the last 2 minutes of the sterilizing hold period, within the accuracy limits of the instrumentation.

G-4.3 The limits for superheating are given in Appendix A.

APPENDIX H

[*Clauses* 2.8, 2.10, 7.11.3, 8.1.3 (b), G-l.1 *and* G-2.4]

THE BOWIE/DICK TAPE TEST FOR POROUS LOAD STERILIZERS

H-l. INTRODUCTION

H-l.1 There will be even and rapid penetration of steam into the load in a porous load sterilizer only if sufficient air and non-condensable gases are removed from the chamber and load before steam is admitted during the sterilizing stage. If air and non-condensable gases are not removed from the chamber and the load or from the steam supply, they may become trapped within the load. This would prevent penetration of that part of the load by steam and consequently, sterilizing conditions may not be achieved.

H-l.2 A method of demonstrating that even and rapid nenetration by steam has occurred is by the use of' thermometric equipment, with thermocouples appropriately placed within the chamber and the load.

H-1.3 This method of testing is not practicable on a daily basis and it was for this reason that the Bowie/Dick tape test was developed. The Bowie/Dick tape test on its own does not confirm that the sterilizing condition have been achieved in the load. The test does prove whether or not the steam penetration of the test pack has been even and rapid and that air or other non-condensable gases were not present and have not entered the test pack Consequently, daily assurance that a porous load sterilizer is functioning correctly is achieved by a combination of tests,. records and observations, of which the Bowie} Dick tape test is only a part. The other tests, records and observations which must be made regularly are considered elsewhere in this document but the vital evidence which can be gathered from each is summarized in the table below. From this table, it can be seen that no **single test** or observation gives conclusive evidence that the sterilizer is processing the load correctly. A satisfactory result from all the tests and observations is necessary for such assurance.

Test, Record or Observation	*Evidence*
1. Temperature record chart for each load	a) Whether the correct number and profile of' pre-sterilization pulses have been obtained.
	b) Whether the correct temperature has been maintained in the chamber for the necessary time.
2. Indicating thermometer	a) Whether the correct temperature has been abtained in the chamber.

Test, Record or Observation	*Evidence*
	b) By comparison of 1 and 2, during steady state conditions whether either instrument is faulty.
3. Air detector function	Whether air and other non-condensable gases are present within a sample of the chamber atmosphere.
4. Bowie/Dick tape test	Whether there has been even and rapid penetration of steam into the test load at the commencement of the sterilizing stage (not necessarily whether a sterilizing temperature/time relationship has been achieved in the load)
5. Leak rate test	Whether the evacuated chamber is adequately sealed.

H-2. TECHNICAL PROCESS ON WHICH THE TEST IS BASED

H-2.1 An adhesive tape which is printed with a chemical substance, is fixed in the shape of a cross to a piece of suitable paper and this test sheet is placed at the centre of a stack of towels (the test pack). The chemical substance shows a colour change related to time and temperature when exposed to phase boundary steam. The depth of colour change is dependent on the time of exposure, the temperature and the moisture. The indicator is much less sensitive to dry heat; exposure to air at 134°C for 3 minutes will cause no discernible colour change whereas exposure to phase boundary steam at 134°C for 3 minutes will cause a marked colour change. To obtain an optimum colour change for interpretation, the Bowie/Dick tape test must not be run for longer than $3\frac{1}{2}$ minutes at 134-138°C. If this period of $3\frac{1}{2}$ minutes is exceeded, the tape may undergo such a colour change as to make it practically impossible to detect colour variations along the tape in a fail condition.

H-2.2 Steam will penetrate rapidly and completely and the tape will show a uniform colour change if all the air is removed. If all the air is not removed before the steam is admitted for the sterilizing stage, the air will collect within the pack as a bubble. The colour of the tape in the region of the bubble will be paler than elsewhere along its length because of the lower temperature and/or reduced moisture level. This will be observed when the paper with the tape cross is examined.

H-2.3 The test pack is chosen since it represents the maximum density of porous load which a sterilizer is designed to process, that is, about 160 kg of fabric material per cubic metre of chamber space. The more air there is to remove, the more exacting will be the test; that is why, the test pack is used by itself in an otherwise empty chamber.

H-2.4 The Bowie/Dick tape test was originally applied to high vacuum sterilizers, in which air removal was effected by a single evacuation of the chamber. Most modern porous load sterilizers employ a pulsing or multistage process to remove air from the chamber and the relevance of the Bowie/Dick tape test to this type of sterilizer is sometimes queried.

H-2.5 It must be emphasized that the test is still valid in these circumstances because the time/temperature characteristics of the steam pulses do not significantly change the colour of the test tape. There is, therefore, no significant danger of obtaining a spurious result unless the air removal stage is unusually long. If the air removal stage exceeds about 15 minutes, the advice of the sterilizer engineer should be sought on the method of performing the Bowie/Dick test so as to ensure its validity.

H-3. MATERIAL USED IN THE TEST

H-3.1 The test is invalid if materials of correct quality are not used. The requirements are.

H-3.1.1 Towels — These must be huckaback towels. After purchase and before use, the towels must be thoroughly washed to remove the dressing. If this is not done, the towels become hardened and their ability to entrap air is diminished.

When towels are washed, they should not be starched, ironed or calendered since this also diminishes the ability of the towels to entrap air. Towels in use should be washed at least once a week.

Towels should be unfolded and hung out for at least an hour between tests so that their humidity is stabilized. The use of slightly damp or compressed towels can result in the test giving a pass result when it should have been a failure. Towels which have become excessively dehydrated may lead to superheating in the pack which might also produce misleading results.

H-3.1.2 *Tape* — The tapes currently recommended are autoclave tapes. Under normal storage conditions, the tape has a 12-month shelf life. Tape which is more than 12 months old should not be used for the Bowie/Dick tape test, but is perfectly satisfactory as a packaging tape/process indicator.

The tape should be stored in cool, dry conditions away from direct sunlight and artificial light.

The exact colour change shown by a processed tape will vary between different rolls and batches of tape; consequently, tape from the same roll should be used for each test.

H-3.1.3 ***Paper*** — The use of waxed, greaseproof or heavily glazed art papers will seriously impair the accuracy of the test. The test sheet may be conveniently standardized on an A4 sheet of white, wood free, duplicator paper (80 g/m^2).

H-4. MAKING UP THE TEST PACK

H-4.1 Each towel should be folded in half, three times, to provide eight thicknesses, each with an area of 300 × 225 mm, and placed one above the other to form a stack about 270 mm high (Fig. 6). The exact number of towels needed will depend on how often they have been used, but 25 to 36 may be needed. A piece of paper to which autoclave tape has been applied in the form of a diagonal cross is placed in the middle of the stack. The format suggested is shown in Fig. 7. It is not necessary to add more tape than is indicated since the use of additional tape may impair the interpretation of the text. The stack may be placed in a dressings casket or in a box made of cardboard or metal which is not airtight. If preferred, the stack can be wrapped in fabric or paper, or it can be secured with tape. Whichever method is used, the towels must stay in position when the test pack is handled. The towels must be laid quite flat with no ridges. When more than 36 towels are needed to give the required height, it indicates that the towels are worn and should be replaced.

H-5. PERFORMING THE TEST

H-5.1 The test pack shall be placed on the longitudinal centre line of the chamber, 100 mm from any door and approximately 100 mm above the chamber base of an otherwise empty sterilizer, with the towels lying horizontally. It must be subjected to a standard sterilizing cycle. The holding or sterilizing time shall not be more than 3½ minutes if a temperature of 134 to 138°C is being used.

H-5.2 The test should normally be carried out under automatic control but if the automatic control is set for a longer holding time than 3½ minutes, the stage must be cut short, for the purpose of the test, by using the manual control. If there is any doubt about how to do this, the engineer should be asked for advice. Machines should be modified, where necessary, with the advice of the sterilizer engineer so that the test can be done under automatic control.

H-5.3 It is important that a warming up cycle is performed on the machine before the test run is started since the effectiveness of air removal may depend on all parts of the sterilizer being at the working temperature. A satisfactory sterilizer may give a fail result if this is not done.

H-6. READING THE TEST

H-6.1 When interpreting the result of the test, it is important to place the corner of the test sheet adjacent to its centre in order to make a direct comparison of the colour indicator density. For the test result to be accepted as a pass, the same colour change must occur along the length of the tape (see Fig. 8) and if there are any discernible differences, the test should be recorded as failed and the paper should be marked accordingly. Where there is a large area of unchanged indicator at the centre of the sheet, this is indicative of a gross failure (see Fig. 9).

H-7. ACTION FOLLOWING THE TEST

H-7.1 The paper from each test should have been marked as indicated above and be kept for reference for 12 months, together with the associated chart from the temperature chart recorder (see Appendix D).

H-7.2 It is important to realize that if a sterilizer fails to pass the Bowie/Dick tape test, it cannot be made safe merely by increasing the holding time until a uniform colour change is produced. Such a sterilizer is in urgent need of skilled attention.

H-7.3 A satisfactory test result does not indicate the ability of the machine to sterilize. It only indicates that the steam will evenly penetrate a load. Satisfactory temperature and pressure readings during the sterilizing stage and an acceptable temperature record chart are required as assurance of sterility.

H-7.4 An unsatisfactory test result indicates that the machine should not be used until the fault has been rectified.

H-7.5 If the sterilizer does not indicate nonsterile when a failed Bowie/Dick tape test is obtained, this implies that the air detector is not working properly. The machine should not be returned to service until the air detector has been overhauled and the machine performance checked by means of independent thermometric equipment (see Appendix A).

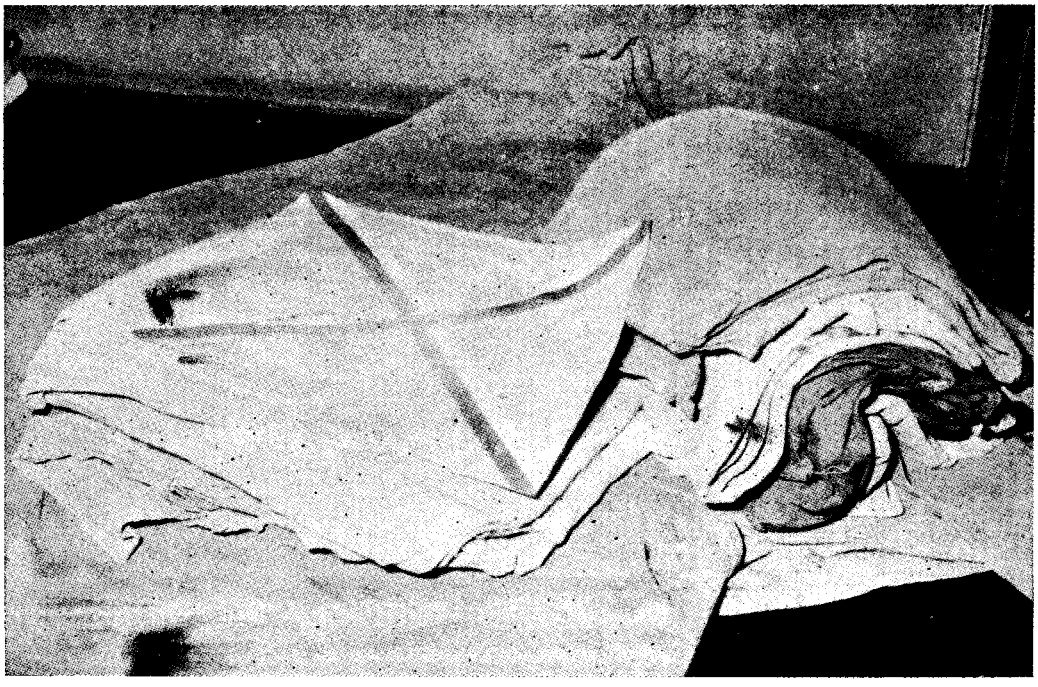


FIG. 6 TOWELS READY FOR TEST

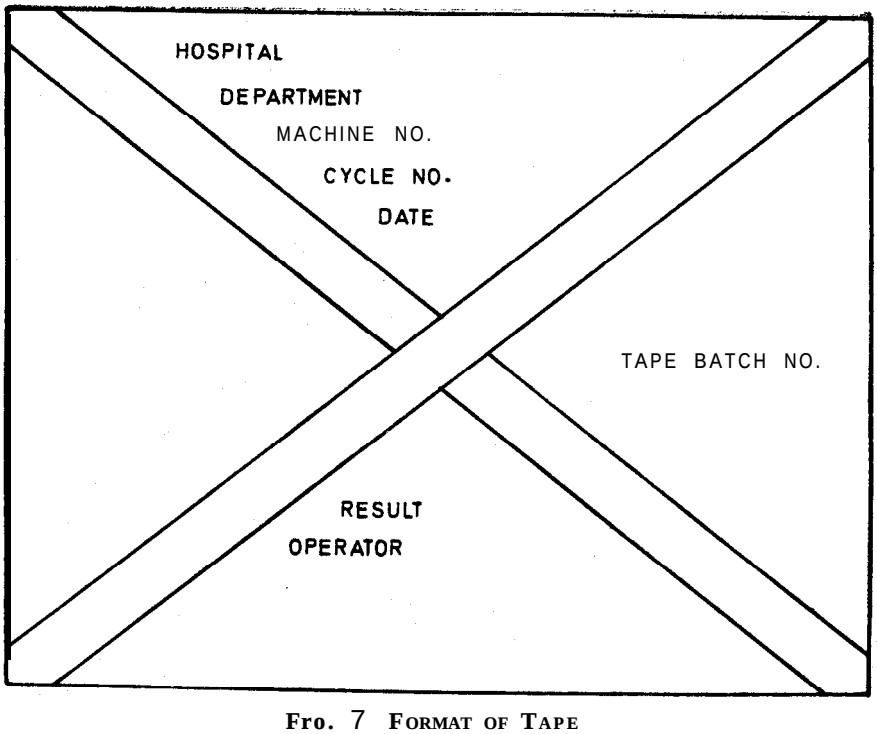


FIG. 7 FORMAT OF TAPE

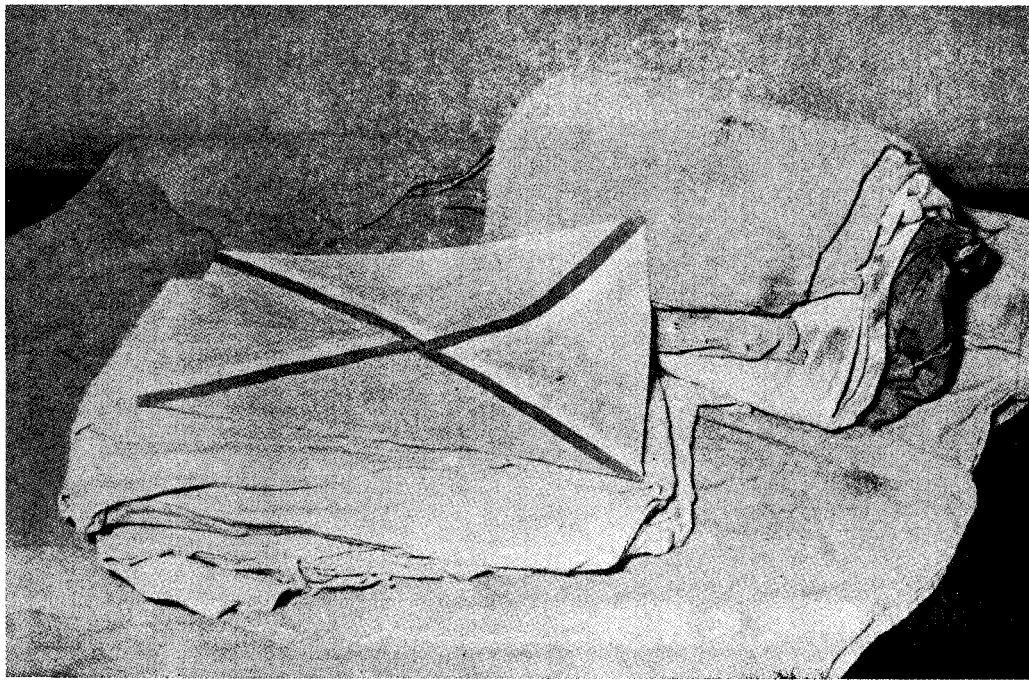


FIG. 8 A SATISFACTORY TEST RESULT

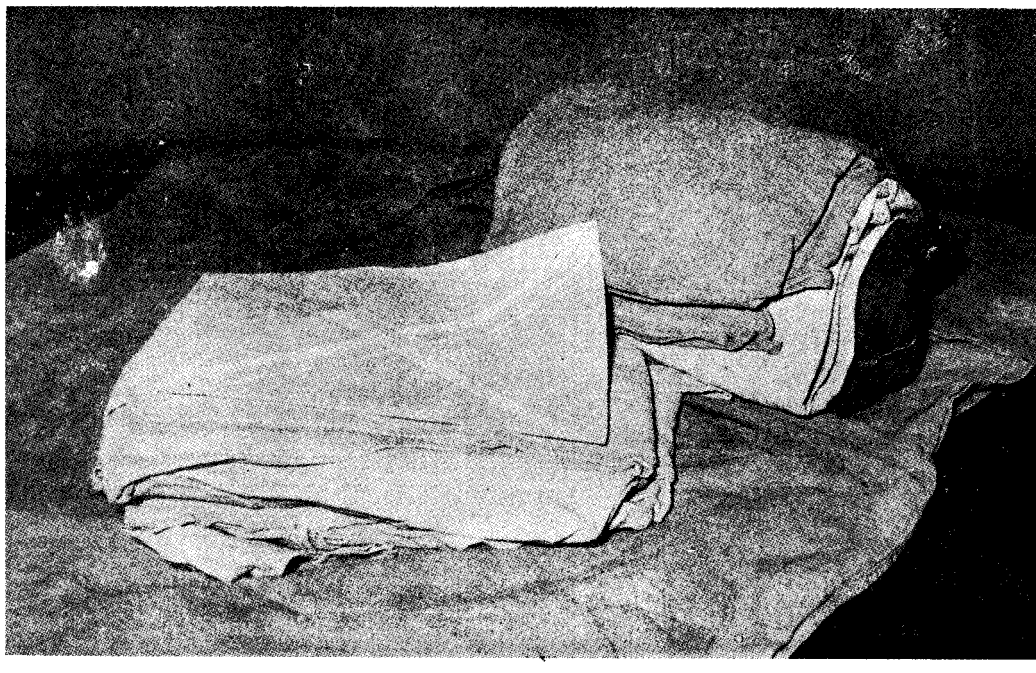


FIG. 9 A FAILED TEST RESULT

APPENDIX J

[Clauses 2.8, 2.10, 7.11.3, 8.1.3 (c), G-l.1 *and* K-1.9.1]

LEAK RATE TEST FOR POROUS LOAD STERILIZERS

J-1. PROCEDURE

J-l.1 This test is applicable only to porous load sterilizers on which it is performed at least weekly.

J-1.2 There are two reasons why leakage of air into the chamber at a rate greater than that specified (see **J-1.9**) is unacceptable. They are as follows:

a) The presence of air prevents proper penetration of load by steam and thus inhibits sterilization, and

b) The air leaking into the chamber at the end of the sterilization stage will not have passed through the bacteria-retentive filter and, therefore, there is a potential risk of re-contaminating the load.

J-l.3 The leak rate test involves the drawing of a vacuum in the chamber, followed by the closure of all valves leading to the chamber, stopping the means of drawing the vacuum and observation of the chamber pressure for a timed period. The manufacturer's instructions should be followed in the conduct 'of the test; in case of doubt, the advice of the sterilizer engineer should be sought. During the leak rate test, it is desirable to record the maximum level of vacuum attained as this gives an indication of the performance capability of the air removal system.

J-l.4 The test requires the use of an absolute pressure gauge. These gauges are usually calibrated to cover the range O-100 mmHg absolute or 0- 150 mbar absolute.

J-l.5 The leak rate test must be carried out when the machine is at normal working temperature, On machines where the test is performed during the drying stage of a completed cycle, a previous full cycle is not necessary.

J-l.6 Most modern sterilizers have an automatic leak test position, operated usually by a key switch on the fascia of the sterilizer. During the test, this switch is turned to the leak test position, the cycle is commenced with an empty chamber and at the appropriate time (usually in the drying stage), the chamber is automatically isolated and the vacuum pump stopped. The vacuum level achieved at this point should be recorded. A period of approximately 5 minutes should be allowed after the pump has stopped for the full closure of valves and for stabilization of conditions in the chamber. The absolute pressure gauge reading should then be recorded and a period of 10 minutes timed (preferably with a stop watch). After this period has elapsed, the absolute pressure gauge reading should again be recorded.

J-l.7 Experience indicates that a leak rate equivalent to a rate of change in pressure of 1·3mbar/minute (1 mm Hg/minute) over a period of 10 minutes after stabilization is the maximum which should normally be permitted. Leak rates in excess of this level tend to create inconsistencies in sterilizer performance.

J-l.8 The leak rate test and the Bowie/Dick tape test are complementary tests. A sterilizer which fails to meet the requirements of either of these tests must not be used until the fault(s) has been rectified and the sterilizer satisfies both of these tests.

J-l.9 Considerable care and knowledge must be applied in the interpretation of results of leak tests. On a typical test, the absolute pressure may rise by 20 mm of Hg or more (for example, 25 mbar) in the first few minutes of the test due to evaporation of moisture remaining in the chamber and connecting pipework. Such a result does not necessarily indicate a leak. If there is an initial rise in pressure due to this evaporation (5 minutes is usually allowed), the test should be continued for a further period of 10 minutes and during this further period, the rise in absolute pressure should be noted.

J-l.10 It is recommended that those sterilizers which are neither technically obsolete nor reaching the end of their useful working life and which are not fitted with an automatic leak test position should be modified to provide this facility. Until the modification has been completed, it may be necessary to ensure that certain hand-operated valves are closed during the tests.

APPENDIX K

(Clauses 2.8, 2.10, 7.11.3, 8.1.3, 10.11.2 *and* G-1 1)

AIR DETECTOR TESTS FOR POROUS LOAD STERILIZERS

K-l. PROCEDURE

K-1.1 An air detector is fitted as part of the control system of a porous load sterilizer. Its function is to monitor the conditions within the chamber to determine whether or not the air present is sufficient to impair the sterilizing process.

NOTE — Some air detectors monitor part and some the whole of the sterilizing stage; others monitor only the start of the sterilization hold stage or some other part of the air removal stage.

K-1.2 A correctly adjusted air detector will contribute to a minimum standard of product security; it should not be regarded as an alternative to effective maintenance.

K-l.3 The air detector does not monitor the residual air in the load. The air detector and the Bowie / Dick tape test are complementary. The air detector should be tested for function only when consistent Bowie/Dick failures occur.

K-l.4 A leak rate test should always precede an air detector test to establish whether or not the leak rate of the sterilizer is within the acceptable limits. (The air detector tests may require the leak rate test procedure to be used.)

K-l.5 There are two air detector tests. These are:

a) *Air Detector Function Test*

1) This test should be undertaken when the air detector performance is suspect. It does not require separate instrumentation other than a simple metering device (for example, a small valve by means of which air may be introduced into the chamber) used in conjunction with the absolute pressure gauge fitted to the sterilizer.

2) The test entails establishing that the air detector will fail a cycle before the maximum leak rate specified by the manufacturer is introduced (the maximum leak rate should be equal to or less than the leak rate established during commissioning which resulted in the temperature measured at the centre of the Bowie/Dick test pack being 2°C lower than the temperature measured in the drain line during the last 3 minutes of the 6 minutes permitted to stage 2).

3) In practice, it is usual to quote the maximum and the minimum of a range of leak rates over which the air detector may be expected to cause indication of a failure to sterilize. These are commonly, pass at 3·0 mbar/minute and fail at 6·0 mbar/minute.

b) *Air Detector Performance Test*

1) This test should be performed during commissioning and also when the air detector has failed a function test. The test requires the use of separate thermometric equipment with thermocouples, one inserted in the geometric centre of a Bowie / Dick test pack, in an otherwise empty chamber, and one in the chamber drain, and in conjunction with either the metering device referred to for the function test.

2) This test entails establishing that the air detector will fail a cycle before the temperature measured at the centre of the test pack differs by more than 2°C from that in the drain during the last 3 minutes of the 6 minutes permitted to stage 2.

K-l.6 Features Common to Both Tests — It is necessary to introduce air into the chamber at a controlled rate whilst one or more cycles are performed under automatic control. Because the different types of air detector may operate at different parts of the cycle, it is usually necessary to regulate the introduction of air into the chamber during a leak rate test by observing the absolute pressure gauge fitted to the sterilizer. The regulating device should be screwed into an entry boss in the front lower part of the chamber.

K-l.7 Particular Features of the Function Test

K-1.7.1 This test is performed with an empty chamber, using the regulating device. During a leak rate test, or otherwise as indicated by the manufacturer, the regulating device should be opened to allow sufficient air in-leakage to result in the maximum change of pressure over a given time interval specified by the manufacturer. The sterilizer should then be operated under automatic control with the regulating device open at this setting. The air detector should then fail the cycle.

K-1.7.2 The sterilizer should be checked at regulating device settings which result in both the maximum and minimum leak rate if the manufacturer specifies a range of leak rates over which the air detector should operate, such as 2 mm / min and 4 mm/min leak rates.

K-1.7.3 If the air detector fails to operate in accordance with the specified parameters, it should be adjusted in accordance with the manufacturer's instruction by personnel who are competent to undertake the work, using separate thermometric equipment, and adopting the performance test procedure.

K-l.8 Particular Features of the Performance Test

K-1.8.1 The sterilizer should be operated under automatic control and the regulating device should be opened up over successive cycles until the 2°C temperature difference between the pack and the drain line is reached. The air detector should fail the cycle either when or before this temperature difference is reached during the last 3 minutes of the 6 minutes permitted to stage 2.

NOTE — Certain designs of air detector have particular characteristics which permit other methods of testing, for example, where the device is sufficiently sensitive to residual air, omission of part of the air removal stage may have the same effect as a deliberately induced leak. In this case, the efficiency of air removal stage should be progressively downgraded until the 2°C depression is obtained.

K-1.8.2 When adjustment of the air detector is necessary, it should be carried out in accordance with the manufacturer's recommendations and only by personnel competent to undertake the work.

K-l.9 Comparison Between Function Test and Performance Test

K-1.9.1 During commissioning or re-commissioning tests, the leak rate required to result in 2°C differential should be measured and noted. This should be equal to or greater than the maximum leak rate specified by the manufacturer.

NOTE 1 — Any change in leak rate necessary to cause the 2°C differential should be recorded in the plant history record? and the new value should be used for subsequent function tests.

NOTE 2 — The leak rate measured in these tests will automatically include any permissible leak rate for a particular machine because the air entering via the regulating valve will be additional to any leaking in at the door seal, etc. Satisfactory air tightness of the chamber, demonstrated by a satisfactory leak rate test as described in Appendix J, is essential to ensure the repeatability and thus the validity of these tests. The regulated part of the total leakage in these tests should be as large as possible. If possible, the door should be left closed between consecutive test runs because it may cause variations between the normal leak rate and the regulated leak introduced in the tests.

APPENDIX L

[*Clauses* **2.8, 2.10, 7.11.3** *and* 8.1.3 (e)]

PERFORMANCE TESTS FOR STERILIZERS FOR FLUIDS IN SEALED CONTAINERS (BOTTLED FLUID STERILIZERS)

L-l. GENERAL

L-l.1 The tests required are those referred to in Appendix D, the records of which are required for batch and day-to-day production control purposes and apply to sterilizers processing sealed bottles. They are as follows:

a) Weekly temperature and automatic process control tests;

b) Quarterly tests; and

c) Yearly, commissioning and re-commissioning tests.

L-1.2 For all these tests, the bottles should be filled with fluid to a level which should normally not exceed 80 percent of their capacity. The temperature of all the filled bottles should be similar before the test is commenced.

L-2. WEEKLY TEMPERATURE AND AUTOMATIC PROCESS CONTROL TEST

L-2.1 One standard batch should be used for the performance of this weekly test. It should be typically representative of all batches normally processed and one for which an MTR has been established during commissioning (see Appendix D). Ideally, the specification of the test batch should be identical to that of a commonly processed batch type so that the test observations may be made during a normal production run. If the test is satisfactory, the batch may be passed into stock.

L-2.2 The sterilizer should be operated under automatic control and the complete test cycle should be observed. At least four readings of chamber temperature and pressure should be taken from the sterilizer instruments at equal time intervals during the sterilization hold time. Observations should also be made of temperatures and pressures at other significant points of the cycle, and the duration of the various stages and sub-stages of the cycle. A record should be made in the plant history record of all these observations.

L-2.3 The test should be considered satisfactory if all the following results are observed:

a) The temperature record chart agrees satisfactorily with the appropriate MTR;

b) The measured parameters are consistent with the previously recorded tests results;

c) The engineer observing the test does not detect any mechanical or other anomaly; and

d) The interlock which prevents opening of the door whilst the load temperature exceeds 80°C, is not released at a point in the cycle significantly before that shown on the MTR.

NOTE — In those cases where it is not physically possible to observe operation of the interlock, it will be necessary to attempt to operate the door mechanism as if to open the door. Very great care must be exercised to ensure that if the door mechanism moves at all, it is moved only just sufficiently to establish whether the interlock is engaged or released. The mechanism must not be allowed to move far enough for the door to be inadvertently opened if the interlock has released before the safe temperature had been reached.

L-3. COMMON REQUIREMENTS FOR QUARTERLY, YEARLY COMMISSIONING AND RE-COMMISSIONING TESTS

L-3.1 Each quarterly, yearly, commissioning and re-commissioning test requires temperature measurements to be recorded by separate thermometric equipment, using thermocouples in test bottles and in the chamber drain. Each thermocouple in a bottle should be on the vertical axis, between 20 and 30 mm above the base of the bottle.

L-3.2 The thermocouple in the chamber drain should be within approximately 100 mm of the exit from the chamber. In the case of a small sterilizer having no drain, this thermocouple should be inserted in an appropriate position within the chamber steam space but below the bottom of the lowest bottle.

NOTE — The thermocouple in the chamber drain should be in contact with condensate at the phase boundary condition. This may sometimes require deeper insertion than the recommended 100 mm.

L-3.3 The test recorder chart should be marked to show the start and finish of the sterilization hold time, details describing the test load, the distribution pattern of the load within the chamber, and the point at which the door may be opened (that is, release of the door interlock mechanism so that the door may be opened).

L-3.4 A temperature and automatic process control test should be carried out in association with these tests, and observations should be made as described under weekly test and recorded.

L-3.5 The tests should be considered satisfactory if all the following results are observed:

a) The thermocouples and fluid remain sealed in the test bottles throughout the cycle;

b) Not more than 1 or 1 percent* (whichever is greater) of the containers composing the load has broken;

c) The temperatures measured are within the permissible limits for sterilization throughout the appropriate sterilization hold time. These are:

Sterilizing Temperature °C	*Time* min
$115 \; ^{+3}_{-0}$	*30*
$121 \; ^{+3}_{-0}$	*15*

d) The temperatures measured differ by not more than 1°C during the last 5 minutes of the sterilization hold time (this indicates that excessive stratification is not occurring within the chamber); and

e) The temperatures measured in the test bottles have fallen to 80°C† or below before the door interlock is released to allow the door to be opened on completion of the cycle [see **L-2.3**(d)].

L-3.6 It should be noted that the total heat energy input to the load over the whole sterilizing cycle and its effect on the product is a matter for the quality controller. However, only in exceptional case will these problems be met in practice.

L-4. ADDITIONAL REQUIREMENTS FOR. QUARTERLY TEST

L-4.1 The sterilizer should be loaded with test bottles to duplicate a batch for which an MTR has previously been established and which has been chosen (normally on a rotating basis with the other standard batches) for this particular test.

L-4.2 Thermocouples should be inserted into the two bottles located in positions established during commissioning where they were slowest to heat up and slowest to cool down. A third thermocouple should be inserted in the drain line.

L-4.3 The complete cycle temperatures should be recorded during a full automatic cycle for the selected test load by a test instrument having a minimum of three channels.

L-5. ADDITIONAL REQUIREMENTS FOR. YEARLY, COMMISSIONING AND RE-COMMISSIONING TESTS

L-5.1 Reference should be made to Appendix D on the selection of test loads. MTRs should be established after commissioning for all batch types to be processed by the sterilizer. **These are** required for production control purposes, the

*The breakage rate for new unprocessed bottles may exceed this.

†This may be higher for non-rigid containers.

yearly and re-commissioning tests. The sterilizer engineer may apply his discretion in the choice of test loads for commissioning, yearly and re-commissioning tests and, in most cases, tests on two repesentative but dissimilar batch types will be sufficient.

L-5.2 The sterilizer should be loaded with test bottles appropriate to the selected test load

L-5.3 Thermocouples should be inserted into bottles which are distributed at eight corners of the load and in a bottle at the centre of the bottom layer. Two additional thermocouples should be inserted, the first in the chamber drain and the second within the upper third of the free chamber space*.

*The temperature distribution of fluids in sealed non-rigid containers should be ascertained during separate tests and thermocouples should be positioned accordingly.

L-5.4 The complete cycle temperature should be recorded during a full automatic cycle, by a test instrument having a minimum of 12 channels.

L-5.5 Attempts to sterilize or disinfect the cooling water do not compensate for inadequately sealed containers nor for containers not designed for processing in rapid-cooled sterilizers. However, if the temperature characteristics of the spray cooling system are required to be known, an additional thermocouple may be inserted either in the spray water inlet pipe to the chamber, within 100 mm of its entry to the chamber, or in the coldest position in the spray water hold tank.

L-5.6 If the temperature of the spray cooling water has been recorded, it should comply with the stated performance specification.

APPENDIX M

[*Clauses* 2.8, 2.10, 7.11.3 and 8.1.3(f)]

PERFORMANCE TESTS FOR STERILIZERS FOR UNWRAPPED INSTRUMENTS AND UTENSILS

M-1. GENERAL

M-1.1 The tests required are those referred to in Appendix D, the records of which are required for batch and day-to-day production control purposes. They are as follows!

a) Weekly temperature and automatic process control test;

b) Quarterly test, and

c) Yearly, commissioning and re-commissioning tests.

M-1.2 For all these tests, the sterilizer should be fully loaded with a mixed load of unwrapped instruments and utensils of the type normally processed. They should be conducted after a warming up cycle has been completed.

M-2. WEEKLY TEMPERATURE AND AUTOMATIC PROCESS CONTROL TEST

M-2.1 It is helpful if the sterilizer is fitted with a chart recorded but this is not essential for satisfactory operation of the sterilizer or for the performance of this test.

M-2.2 The sterilizer should be operated under automatic control and the complete test cycle observed. At least three sterilizer instrument readings of chamber temperature and pressure should be taken at equal time intervals during the sterilization hold time. Observations should also be made of temperatures and pressures at other significant points of the cycle and the duration of various stages or sub-stages of the cycle. An entry should be made in the plant history record of all these observations.

M-2.3 The test should be considered satisfactory if all the following requirements are met:

a) The measured parameters are consistent with previously recorded test results (particular note should be made of the final vacuum level on machines having a vacuum drying stage);

b) The engineer observing the test does not detect mechanical or any other anomaly; and

c) The load, when removed from the chamber, is sensibly dry.

M-3. COMMON REQUIREMENTS FOR QUARTERLY, YEARLY, COMMISSIONING AND RE-COMMISSIONING TESTS

M-3.1 Each of these tests requires that temperature measurements be recorded by separate thermometric equipment, using a minimum of two thermocouples. The thermocouples should be placed, one in the chamber drain within approximately 100 mm of the exit from the chamber and the other in contact with the surface of a representative load item, for example, closing a pair of large forceps on to it. In the case of a small sterilizer having no drain, the former should

be inserted in an appropriate position within the chamber, air vent, discharge pipe or adjacent to it.

NOTE — The thermocouple in the chamber drain should be in contact with the condensate at the phase boundary condition. This may sometimes require deeper insertion than the recommended 100 mm.

M-3.2 A temperature and automatic process control test should be carried out in association with these tests, and observations should be made as described under weekly test and recorded.

M-3.3 The tests should be considered satisfactory if all the following requirements are met:

a) The temperatures in the drain and of the representative load item are within the limits of 134 $^{4}_{0}$°C during a continuous period of 3 minutes of stage 2,

b) The temperature of the representative load item does not differ by more than 2°C from that of the chamber drain during that 3-minute period, and

c) Either of the following applies:

1) The cycle is completed in not more than 10 minutes for those machines supplied with steam from an external source, or

2) It should be possible to complete 16 cycles within a period of 4 hours, for bench type machines having integral electrically heated elements. (It may not be necessary to complete 16 cycles in order to ensure that the sterilizer will pass this test.) A sterilizer which completes 4 cycles from cold in one hour will clearly pass this test (*see* M-4.1).

NOTE — It is anticipated that tests for small electrically heated bench top bowl and instrument sterilizers will not take place at the user site but that the sterilizer will be exchanged for a spare machine and will be removed to a suitable central location for maintenance and test purposes.

M-4. YEARLY, COMMISSIONING AND RE-COMMISSIONING TESTS

M-4.1 The alternative test at M-3.3 (c) (2) should, ideally, be continued for full 4 hours to ensure that the temperature of water in the reservoir does not exceed 90°C with an ambient air temperature of between 20 and 25°C. If the rate of temperature rise is observed to be satisfactory (say 3 or 4°C per cycle), the tests may be discontinued after 3 or 4 cycles. This does not apply to reservoirs within the chamber.

M-4.2 A third thermocouple should be inserted into the upper third of the free chamber space for detecting the superheat.

M-4.3 The limits for superheating are given in Appendix A.

APPENDIX N

(*Clauses* 2.8, 2.10, 7.11.3, 8.1.3, 11.5.1 *and* B-9.1)

PERFORMANCE TESTS FOR HOT AIR STERILIZERS

N-1. PROCEDURE

N-1.1 There are two tests for hot air sterilizers:

a) Basic performance test, and

b) Production load test.

N-1.2 The manufacturer should certify that the sterilizer has satisfactorily passed the basic performance test.

N-1.3 The sterilizer engineer should witness any tests performed on site by the manufacturer.

N-1.4 The basic performance tests should be carried out by the sterilizer engineer:

a) after any modification which may affect the performance; and

b) when the production load test result has proved unsatisfactory.

NOTE — An unsatisfactory loading pattern may result in a sterilizer failing the production load test but passing the basic performance test; individual load items or containers should be disposed within the chamber in a manner which permits good air circulation. In such cases, it will be necessary to redistribute the load and carry out additional tests until a loading pattern is established which enables the sterilizer to pass the production load test.

N-1.5 If the results of the basic performance test are unsatisfactory, the department should be advised accordingly.

N-1.6 The sterilizer engineer should carry out the production load test on all sterilizers to establish the heat up time and to prepare the MTR.

N-I.7 A 12-channel recorder is normally adequate for both tests; one thermocouple should either be attached or close to the sensor which serves the sterilizer chart recorder and a second should either be attached or close to the sensor for the

sterilizer thermometer. The remaining 10 thermocouples are located at test positions disposed throughout the load.

N-2. PRODUCTION LOAD TEST

N-2.1 In general, an MTR may be established for the worst case load, that is, that which will require the longest time to reach the sterilizing temperature throughout. If the worst case MTR is used for smaller loads, they may well be held at the sterilizing temperature for prolonged periods, In the majority of cases, the extra time at temperature will not affect the items processed and the extended time will not, therefore, be a practical disadvantage. Where prolonged heating can cause deterioration of load items (for example, certain medicinal products), they should be processed by a separate operating cycle with its own specific MTR.

N-2.2 The test should be performed with the worst case load (and any specific load) for which the sterilizer is to be used.

N-2.3 Two thermocouples are located as in N-1.7. For the remaining 10 thermocouples, a *series of* preparatory tests may be required to establish which specific items within the test load show the widest temperature variation; these will normally be at the corners of the chamber and at the centre of each' shelf. Once a distribution pattern for the thermocouples has been established, it should be used in all subsequent tests for that load type.

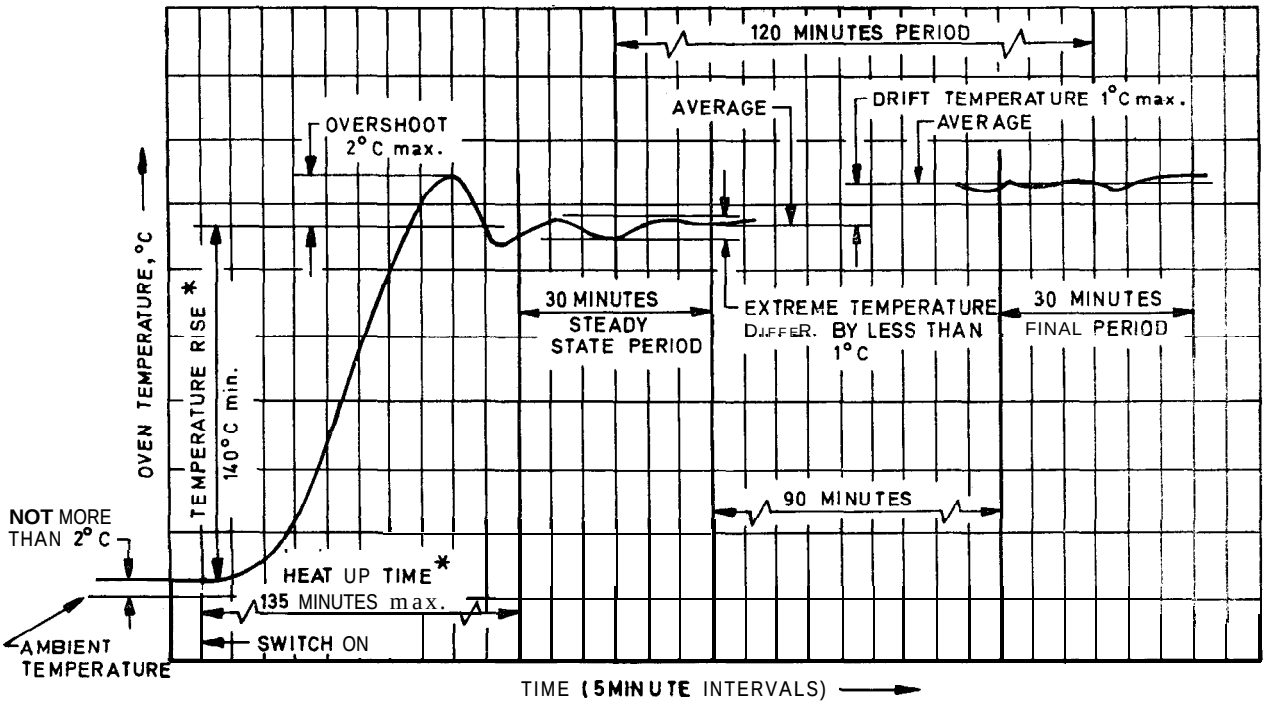
N-2.4 If the load consists of non-volatile fluids or powders, the thermocouples should be inserted through the caps or the lids of the containers so as to be at the centre of the contents. If the load consists of glass ampoules, the thermocouples should be inserted into them and sealed in position by means of a heat stable sealant.

N-2.5 If the load item is an instrument in a container, the thermocouple should be in intimate contact with the instrument.

N-2.6 The multichannel recorder should monitor a complete cycle in each of the tests.

N-2.7 The parameters are defined as follows:

a) *Temperature Overshoot* — It is first necessary to identify the steady state period. The steady state period is the first total period of 30 minutes during which the temperature varies by not more than 1°C. Under certain conditions, the temperature before the steady state has been reached is greater than the steady state average; when this occurs, the difference between the maximum temperature attained and the steady state average is the temperature overshoot (see Fig. 10).



***Heat up time is the additional parameter to be identified for a 140°C temperature rise during a basic performance test.**

NOTE 1 — The recording will normally be that obtained from a multichannel 'dotting' instrument which will also show the test jar thermocouple temperatures.

NOTE 2 — The illustration represents the recording obtained from the thermocouple in contact with the sterilizer chart recorder sensing element, and indicates which significant parameters require to be identified.

NOTE 3 — The illustration shows both overshoot, and ripple, neither of which may be evident in a test because of thermal hysteresis effects.

FIG. 10 TEMPERATURE OVERSHOOT CURVE

NOTE — Temperature overshoot as defined in IS :3119-1978* should be used as a guide for establishing MTRs. In practice, it may be found that the 2°C limit may be exceeded by virtue of the load distribution. The disposition of load items should not, however, result in overshoot in excess of 5°C.

b) In a repeat test, the chamber temperature as indicted by the thermocouple attached to the sensor of the sterilizer chart recorder and the thermocouple attached to the sensor of the sterilizer thermometer are reproduced to within 1°C of their previous reading (the tests to determine reproducibility may be performed independently with an empty chamber); and

c) When tested during a separate test, the overheat cut-out operates satisfactorily.

NOTE — This test may be carried out with an empty chamber and either by setting the chamber control thermostat above 200°C or by preventing its operation. The temperature is measured in this test by means of the thermocouple in contact with the chart recorder element.

N-2.10 Tests to determine all these parameters may be performed simultaneously. Therefore, if the recorder is of the multichannel dotting type care is required when scrutinizing the resultant traces. For each of these tests, it is necessary to identify separately the trace obtained from the thermocouple attached to the sterilizer chart recorder sensing element.

N-2.11 All the multichannel recorder charts should be retained as part of the commissioning documents. These records should include details of the worst case test load as follows:

a) Type of product;

b) Size, volume and type of container or wrapping material;

c) Number of product items;

d) Distribution within the chamber;

e) Shelving system used; and

f) Location of thermocouples used in the test to establish the MTR.

N-3. ESTABLISHING THE MTR

N-3.1 The TRC obtained during the final satisfactory worst case load test can be used for the production of MTR.

N-3.2 The MTR should be annotated to show the details in N-2.11 and:

a) The description of the worst case load;

b) The thermostat setting to ensure all parts of the load reach temperature and to account for temperature variation (the coldest load item may be 5°C below the temperature recorder on the MTR); and

c) The timer setting to ensure heat-up of all load items and exposure to the sterilizing temperature for the appropriate time.

NOTE — Tests undertaken to establish an MTR should commence with the sterilizer and load temperature within 2°C of the ambient temperature.

N-3.3 The number of MTRs required is a matter of agreement between the sterilizer engineer and the operator. Only one MTR should be in use for each sterilizer unless products are likely to be adversely affected by extended heating (see N-2.1).

N-4. HALF-YEARLY TEST

N-4.1 For this test, a 3-channel temperature recorder may be used and the test should be performed using the worst case load for which the MTR has been established.

N-4.2 Two thermocouples should be placed as in N-1.7 the third being used to measure the temperature of a load item located in one of the positions used during the commissioning tests.

N-4.3 The test should be considered satisfactory if all the following requirements are met:

a) The test requirements of N-2.9 are met [except for item (c)], and

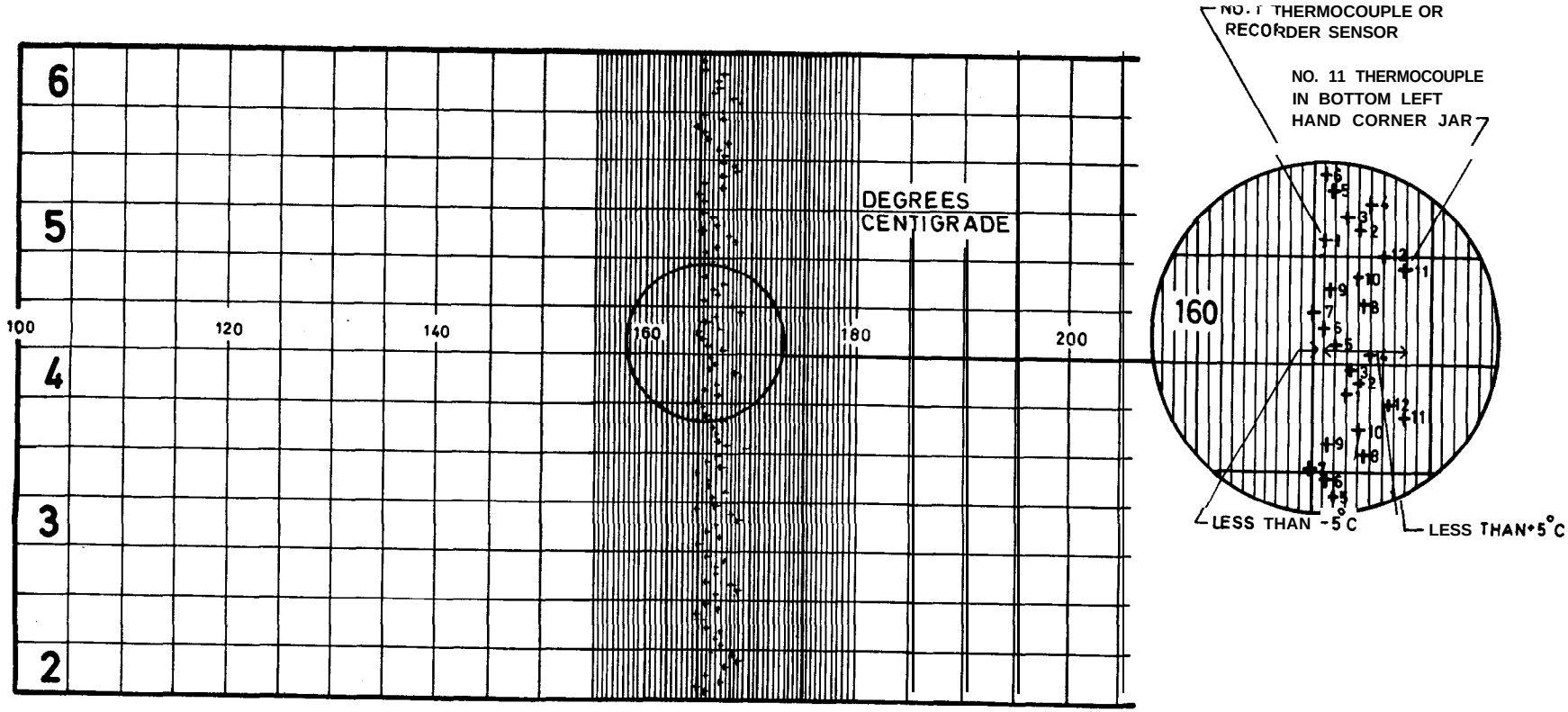
b) The temperature of the load item is within 2°C of the temperature measured at the same position during the commissioning or re-commissioning tests.

N-5. YEARLY TEST

N-5.1 For this test, a 12-channel recorder is required and the test should be conducted with the. worst case load for which the MTR was established.

N-5.2 The test should be considered satisfactory if all the requirements of N-2.9 are met.

*Specification for hot air sterilizers (*first revision*).



In this test the temperature variation was +3·5°C and −0·5°C. A temperature variation of ±5°C is acceptable.

FIG. 11 TYPICAL (GOOD) 12 CHANNEL RECORDING AND SHOWS THE DISTRIBUTION OF TEST JAR TEMPERATURE

APPENDIX P

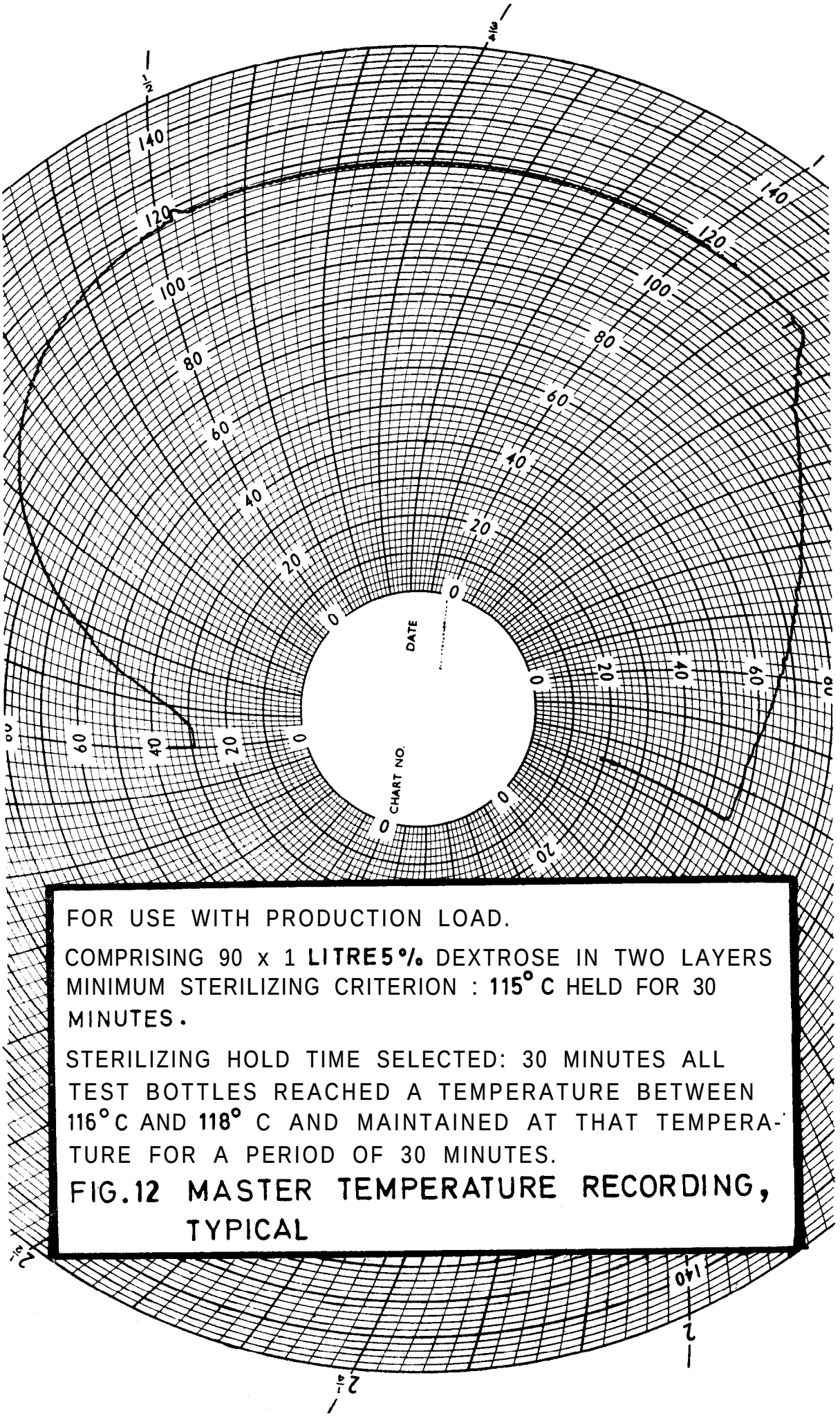
(Clauses 3.1.6 and 11.5.1)

TYPICAL MASTER TEMPERATURE RECORD

P-l. GENERAL

P-l.1 A typical master temperature record is shown in Fig. 12. This is a copy of the chart from the sterilizer chart recorder. A simultaneous temperature recording using a 12-channel chart recorder was used to validate the MTR; the 12-channel chart recording showed that the temperatures of fluid in the test bottles varied between 116 and 118°C at the start of the sterilization hold time. These temperatures were maintained within the sterilization temperature limits for a period of 30 minutes, and during the last 5 minutes of the 30 minutes hold time were all within 1°C.

P-l.2 The sensor of the sterilizer recorder responded to the temperature at one point, in this case the chamber drain; the MTR is, therefore, an analogue, representing a time/temperature profile of a satisfactory sterilization cycle with which all subsequent production load TRCs for similar loads can be compared.



FOR USE WITH PRODUCTION LOAD.

COMPRISING 90 x 1 LITRE 5% DEXTROSE IN TWO LAYERS MINIMUM STERILIZING CRITERION : 115° C HELD FOR 30 MINUTES.

STERILIZING HOLD TIME SELECTED: 30 MINUTES ALL TEST BOTTLES REACHED A TEMPERATURE BETWEEN 116° C AND 118° C AND MAINTAINED AT THAT TEMPERATURE FOR A PERIOD OF 30 MINUTES.

FIG. 12 MASTER TEMPERATURE RECORDING, TYPICAL

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002

Telephones : 3310131, 3311375 — **Telegrams : Manakaanstha (Common to all offices)**

Regional Offices:	**Telephone**
Central: Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 10002	**3310131) 3311375**
***Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola, CALCUTTA 700054**	**362499**
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	**21843, 31641**
Southern : C. I. T. Campus, MADRAS 600113	**412442, 412519, 412916**
†Western : Manakalaya, E9 MIDC, Marol, Andheri (East), BOMBAY 400093	**6329295**
Branch Offices:	
'Pushpak', Nurmohamed Shalkh Marg, Khanpur, AHMADABAD 380001	**26348, 28349**
Peenya Industrial Area, Ist Stage, Bangalore-Tumkur Road, BANGALORE 560058	**384955, 384956**
Gangotri Complex, 5th Floor, Bhadbhada Road, T. T. Nagar, BHOPAL 462003	**66716**
Plot No. 82/83, Lewis Road, BHUBANESHWAR 751002	**53627**
53/5 Ward No. 29, R. G. Barua Road, 5th Byelane, GUWAHATI 781003	**—**
5-8-56C L. N. Gupta Marg (Nampally Station Road), HYDERABAD 500001	**231083**
R14 Yudhister Marg, C Scheme, JAIPUR 302005	**63471, 69832**
117/418 B Sarvodaya Nagar, KA NPUR 208005	**216876, 218292**
Patliputra Industrial Estate, PATNA 800013	**62305**
T.C. No. 14/1421, University P.O., Palayam, TRIVANDRUM 695035	**62104, 62117**
Inspection Offices (With Sale Point):	
'Pushpanjali', First Floor, 205A West High Court Road, Shankar Nagar Square, NAGPUR 440010	**25171**
Institution of Engineers (India) Building, 1332 Shivaji Nagar, Pune 411005	**52435**

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